Clinical trial results:
A randomised, double-blind, placebo-controlled, 3 way, incomplete block cross over study in subjects with allergic rhinitis to assess the effect of once daily single and repeat doses of intranasal Fluticasone furoate/Levocabastine fixed dose combination (FDC) relative to Levocabastine and Fluticasone furoate alone on the onset and magnitude of symptoms of rhinitis in an allergen challenge chamber

Summary

EudraCT number	2013-002940-94
Trial protocol	AT
Global end of trial date	20 February 2014

Results information

Result version number	v1 (current)
This version publication date	27 April 2016
First version publication date	09 February 2015

Trial information

Trial identification

Sponsor protocol code	200286

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 February 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	20 February 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Effect of 8 day treatment with intranasal FF/levocabastine on nasal symptoms elicited by an allergen chamber challenge in subjects with allergic rhinitis when
administered once daily compared with FF and levocabastine alone.

Protection of trial subjects:

Safety assessments at screen, Day 1, Day 8 and follow up.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 November 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 71
Worldwide total number of subjects	71
EEA total number of subjects	71

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	71
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants (par.) who met the eligibility criteria at Screening were randomized to 1 of 18 treatment sequences. The treatment phase was comprised of three 8-day treatment periods, each separated by a 14- to 28-day washout period.

Period 1

Period 1 title	Treatment Period 1 (8 days) (Overall)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst

Arms

Are arms mutually exclusive?	Yes
Arm title	Sequence 1: Levo 200 µg, FF 100 µg/Levo 200 µg, placebo

Arm description:

Participants received levocabastine (Levo) 200 micrograms (µg), fluticasone furoate (FF) 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg once daily (OD) in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 2: Levo 200 µg, FF 100 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received Levo 200 µg, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per

spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 3: Levo 200 µg, FF 100 µg/Levo 200 µg, FF 100 µg

Arm description:

Participants received Levo 200 µg, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details: 25µg/50 µg once daily	

Arm title	Sequence 4: Placebo, FF 100 µg, FF 100 µg/Levo 200 µg
Arm description: Participants received placebo, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.	
Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 5: Placebo, FF 100 µg/Levo 200 µg, Levo 200 µg
Arm description: Participants received placebo, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.	
Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution

Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 6: FF 100 µg/Levo 200 µg, Placebo, Levo 200 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, placebo and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 7: FF 100 µg, Placebo 200 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received FF 100 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 8: FF 100 µg/Levo 200 µg, FF 100 µg, Placebo

Arm description:

Participants received FF 100 µg/Levo 200 µg, FF 100 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 9: Placebo, FF 100 µg/Levo 200 µg, FF 100 µg

Arm description:

Participants received placebo, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo

Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 10: FF 100 µg, FF 100 µg/Levo 200 µg, Levo 200 µg

Arm description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 11: Levo 200 µg, Placebo, FF 100 µg/Levo 200 µg

Arm description:

Participants received Levo 200 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 12: FF 100 µg/Levo 200 µg, Levo 200 µg, FF 100 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution

Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 13: FF 100 µg/Levo 200 µg, Levo 200 µg, Placebo

Arm description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 14: FF 100 µg, FF 100 µg/Levo 200 µg, Placebo

Arm description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution

Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 15: FF 100 µg/Levo 200 µg, FF 100 µg, Levo 200 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, FF 100 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 16: FF 100 µg/Levo 200 µg, Placebo, FF 100 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, placebo and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 17: FF 100 µg, Levo 200 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received FF 100 µg, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 18: Placebo, Levo 200 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received placebo, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo

Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	

Number of subjects in period 1	Sequence 1: Levo 200 µg, FF 100 µg/Levo 200 µg, placebo	Sequence 2: Levo 200 µg, FF 100 µg, FF 100 µg/Levo 200 µg	Sequence 3: Levo 200 µg, FF 100 µg/Levo 200 µg, FF 100 µg
Started	3	6	6
Completed	3	6	6

Number of subjects in period 1	Sequence 4: Placebo, FF 100 µg, FF 100 µg/Levo 200 µg	Sequence 5: Placebo, FF 100 µg/Levo 200 µg, Levo 200 µg	Sequence 6: FF 100 µg/Levo 200 µg, Placebo, Levo 200 µg
Started	3	3	2
Completed	3	3	2

Number of subjects in period 1	Sequence 7: FF 100 µg, Placebo 200 µg, FF 100 µg/Levo 200 µg	Sequence 8: FF 100 µg/Levo 200 µg, FF 100 µg, Placebo	Sequence 9: Placebo, FF 100 µg/Levo 200 µg, FF 100 µg
Started	3	3	3
Completed	3	3	3

Number of subjects in period 1	Sequence 10: FF 100 µg, FF 100 µg/Levo 200 µg, Levo 200 µg	Sequence 11: Levo 200 µg, Placebo, FF 100 µg/Levo 200 µg	Sequence 12: FF 100 µg/Levo 200 µg, Levo 200 µg, FF 100 µg
Started	6	3	6

Completed	6	3	6

Number of subjects in period 1	Sequence 13: FF 100 µg/Levo 200 µg, Levo 200 µg, Placebo	Sequence 14: FF 100 µg, FF 100 µg/Levo 200 µg, Placebo	Sequence 15: FF 100 µg/Levo 200 µg, FF 100 µg, Levo 200 µg
Started	3	3	6
Completed	3	3	6

Number of subjects in period 1	Sequence 16: FF 100 µg/Levo 200 µg, Placebo, FF 100 µg	Sequence 17: FF 100 µg, Levo 200 µg, FF 100 µg/Levo 200 µg	Sequence 18: Placebo, Levo 200 µg, FF 100 µg/Levo 200 µg
Started	3	6	3
Completed	3	6	3

Period 2

Period 2 title	Washout Period 1 (14 to 28 days)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst

Arms

Are arms mutually exclusive?	Yes
Arm title	Sequence 1: Levo 200 µg, FF 100 µg/Levo 200 µg, placebo

Arm description:

Participants received Levo 200 µg, FF 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 2: Levo 200 µg, FF 100 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received Levo 200 µg, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 3: Levo 200 µg, FF 100 µg/Levo 200 µg, FF 100 µg

Arm description:

Participants received Levo 200 µg, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 4: Placebo, FF 100 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received placebo, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 5: Placebo, FF 100 µg/Levo 200 µg, Levo 200 µg

Arm description:

Participants received placebo, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo

Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 6: FF 100 µg/Levo 200 µg, Placebo, Levo 200 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, placebo and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 7: FF 100 µg, Placebo 200 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received FF 100 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 8: FF 100 µg/Levo 200 µg, FF 100 µg, Placebo

Arm description:

Participants received FF 100 µg/Levo 200 µg, FF 100 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution

Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 9: Placebo, FF 100 µg/Levo 200 µg, FF 100 µg

Arm description:

Participants received placebo, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 10: FF 100 µg, FF 100 µg/Levo 200 µg, Levo 200 µg

Arm description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution

Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 11: Levo 200 µg, Placebo, FF 100 µg/Levo 200 µg

Arm description:

Participants received Levo 200 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 12: FF 100 µg/Levo 200 µg, Levo 200 µg, FF 100 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 13: FF 100 µg/Levo 200 µg, Levo 200 µg, Placebo

Arm description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 14: FF 100 µg, FF 100 µg/Levo 200 µg, Placebo

Arm description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo

Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 15: FF 100 µg/Levo 200 µg, FF 100 µg, Levo 200 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, FF 100 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 16: FF 100 µg/Levo 200 µg, Placebo, FF 100 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, placebo and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 17: FF 100 µg, Levo 200 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received FF 100 µg, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution

Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 18: Placebo, Levo 200 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received placebo, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Number of subjects in period 2	Sequence 1: Levo 200 µg, FF 100 µg/Levo 200 µg, placebo	Sequence 2: Levo 200 µg, FF 100 µg, FF 100 µg/Levo 200 µg	Sequence 3: Levo 200 µg, FF 100 µg/Levo 200 µg, FF 100 µg
Started	3	6	6
Completed	3	6	6

Number of subjects in period 2	Sequence 4: Placebo, FF 100 µg, FF 100 µg/Levo 200 µg	Sequence 5: Placebo, FF 100 µg/Levo 200 µg, Levo 200 µg	Sequence 6: FF 100 µg/Levo 200 µg, Placebo, Levo 200 µg
Started	3	3	2
Completed	3	3	2

Number of subjects in period 2	Sequence 7: FF 100 µg, Placebo 200 µg, FF 100 µg/Levo 200 µg	Sequence 8: FF 100 µg/Levo 200 µg, FF 100 µg, Placebo	Sequence 9: Placebo, FF 100 µg/Levo 200 µg, FF 100 µg
Started	3	3	3
Completed	3	3	3

Number of subjects in period 2	Sequence 10: FF 100 µg, FF 100 µg/Levo 200 µg, Levo 200 µg	Sequence 11: Levo 200 µg, Placebo, FF 100 µg/Levo 200 µg	Sequence 12: FF 100 µg/Levo 200 µg, Levo 200 µg, FF 100 µg
Started	6	3	6
Completed	6	3	6

Number of subjects in period 2	Sequence 13: FF 100 µg/Levo 200 µg, Levo 200 µg, Placebo	Sequence 14: FF 100 µg, FF 100 µg/Levo 200 µg, Placebo	Sequence 15: FF 100 µg/Levo 200 µg, FF 100 µg, Levo 200 µg
Started	3	3	6
Completed	3	3	6

Number of subjects in period 2	Sequence 16: FF 100 µg/Levo 200 µg, Placebo, FF 100 µg	Sequence 17: FF 100 µg, Levo 200 µg, FF 100 µg/Levo 200 µg	Sequence 18: Placebo, Levo 200 µg, FF 100 µg/Levo 200 µg
Started	3	6	3
Completed	3	6	3

Period 3

Period 3 title	Treatment Period 2 (8 days)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst

Arms

Are arms mutually exclusive?	Yes
Arm title	Sequence 1: Levo 200 µg, FF 100 µg/Levo 200 µg, placebo

Arm description:

Participants received Levo 200 µg, FF 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo

Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 2: Levo 200 µg, FF 100 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received Levo 200 µg, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 3: Levo 200 µg, FF 100 µg/Levo 200 µg, FF 100 µg

Arm description:

Participants received Levo 200 µg, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 4: Placebo, FF 100 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received placebo, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution

Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 5: Placebo, FF 100 µg/Levo 200 µg, Levo 200 µg

Arm description:

Participants received placebo, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 6: FF 100 µg/Levo 200 µg, Placebo, Levo 200 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, placebo and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution

Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 7: FF 100 µg, Placebo 200 µg, FF 100 µg/Levo 200 µg
Arm description: Participants received FF 100 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.	
Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 8: FF 100 µg/Levo 200 µg, FF 100 µg, Placebo
Arm description: Participants received FF 100 µg/Levo 200 µg, FF 100 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.	
Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 9: Placebo, FF 100 µg/Levo 200 µg, FF 100 µg

Arm description:

Participants received placebo, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 10: FF 100 µg, FF 100 µg/Levo 200 µg, Levo 200 µg

Arm description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo

Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 11: Levo 200 µg, Placebo, FF 100 µg/Levo 200 µg

Arm description:

Participants received Levo 200 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 12: FF 100 µg/Levo 200 µg, Levo 200 µg, FF 100 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 13: FF 100 µg/Levo 200 µg, Levo 200 µg, Placebo

Arm description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution

Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 14: FF 100 µg, FF 100 µg/Levo 200 µg, Placebo

Arm description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 15: FF 100 µg/Levo 200 µg, FF 100 µg, Levo 200 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, FF 100 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution

Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 16: FF 100 µg/Levo 200 µg, Placebo, FF 100 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, placebo and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 17: FF 100 µg, Levo 200 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received FF 100 µg, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 18: Placebo, Levo 200 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received placebo, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	

Number of subjects in period 3	Sequence 1: Levo 200 µg, FF 100 µg/Levo 200 µg, placebo	Sequence 2: Levo 200 µg, FF 100 µg, FF 100 µg/Levo 200 µg	Sequence 3: Levo 200 µg, FF 100 µg/Levo 200 µg, FF 100 µg
Started	3	6	6
Completed	3	5	6
Not completed	0	1	0
Consent withdrawn by subject	-	1	-

Number of subjects in period 3	Sequence 4: Placebo, FF 100 µg, FF 100 µg/Levo 200 µg	Sequence 5: Placebo, FF 100 µg/Levo 200 µg, Levo 200 µg	Sequence 6: FF 100 µg/Levo 200 µg, Placebo, Levo 200 µg
Started	3	3	2
Completed	3	3	2
Not completed	0	0	0
Consent withdrawn by subject	-	-	-

Number of subjects in period 3	Sequence 7: FF 100 µg, Placebo 200 µg, FF 100 µg/Levo 200 µg	Sequence 8: FF 100 µg/Levo 200 µg, FF 100 µg, Placebo	Sequence 9: Placebo, FF 100 µg/Levo 200 µg, FF 100 µg
Started	3	3	3
Completed	3	3	3
Not completed	0	0	0
Consent withdrawn by subject	-	-	-

Number of subjects in period 3	Sequence 10: FF 100 µg, FF 100 µg/Levo 200 µg, Levo 200 µg	Sequence 11: Levo 200 µg, Placebo, FF 100 µg/Levo 200 µg	Sequence 12: FF 100 µg/Levo 200 µg, Levo 200 µg, FF 100 µg
Started	6	3	6
Completed	6	3	6
Not completed	0	0	0
Consent withdrawn by subject	-	-	-

Number of subjects in period 3	Sequence 13: FF 100 µg/Levo 200 µg, Levo 200 µg, Placebo	Sequence 14: FF 100 µg, FF 100 µg/Levo 200 µg, Placebo	Sequence 15: FF 100 µg/Levo 200 µg, FF 100 µg, Levo 200 µg
Started	3	3	6
Completed	3	3	6
Not completed	0	0	0
Consent withdrawn by subject	-	-	-

Number of subjects in period 3	Sequence 16: FF 100 µg/Levo 200 µg, Placebo, FF 100 µg	Sequence 17: FF 100 µg, Levo 200 µg, FF 100 µg/Levo 200 µg	Sequence 18: Placebo, Levo 200 µg, FF 100 µg/Levo 200 µg
Started	3	6	3
Completed	3	5	3
Not completed	0	1	0
Consent withdrawn by subject	-	1	-

Period 4

Period 4 title	Washout Period 2 (14 to 28 days)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst

Arms

Are arms mutually exclusive?	Yes
Arm title	Sequence 1: Levo 200 µg, FF 100 µg/Levo 200 µg, placebo

Arm description:

Participants received Levo 200 µg, FF 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 2: Levo 200 µg, FF 100 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received Levo 200 µg, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo

Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 3: Levo 200 µg, FF 100 µg/Levo 200 µg, FF 100 µg

Arm description:

Participants received Levo 200 µg, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 4: Placebo, FF 100 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received placebo, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 5: Placebo, FF 100 µg/Levo 200 µg, Levo 200 µg

Arm description:

Participants received placebo, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution

Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 6: FF 100 µg/Levo 200 µg, Placebo, Levo 200 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, placebo and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 7: FF 100 µg, Placebo 200 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received FF 100 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution

Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 8: FF 100 µg/Levo 200 µg, FF 100 µg, Placebo

Arm description:

Participants received FF 100 µg/Levo 200 µg, FF 100 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 9: Placebo, FF 100 µg/Levo 200 µg, FF 100 µg

Arm description:

Participants received placebo, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 10: FF 100 µg, FF 100 µg/Levo 200 µg, Levo 200 µg

Arm description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 11: Levo 200 µg, Placebo, FF 100 µg/Levo 200 µg

Arm description:

Participants received Levo 200 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo

Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 12: FF 100 µg/Levo 200 µg, Levo 200 µg, FF 100 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 13: FF 100 µg/Levo 200 µg, Levo 200 µg, Placebo

Arm description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 14: FF 100 µg, FF 100 µg/Levo 200 µg, Placebo

Arm description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution

Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 15: FF 100 µg/Levo 200 µg, FF 100 µg, Levo 200 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, FF 100 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 16: FF 100 µg/Levo 200 µg, Placebo, FF 100 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, placebo and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution

Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 17: FF 100 µg, Levo 200 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received FF 100 µg, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 18: Placebo, Levo 200 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received placebo, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	

Number of subjects in period 4	Sequence 1: Levo 200 µg, FF 100 µg/Levo 200 µg, placebo	Sequence 2: Levo 200 µg, FF 100 µg, FF 100 µg/Levo 200 µg	Sequence 3: Levo 200 µg, FF 100 µg/Levo 200 µg, FF 100 µg
Started	3	5	6
Completed	3	5	6

Number of subjects in period 4	Sequence 4: Placebo, FF 100 µg, FF 100 µg/Levo 200 µg	Sequence 5: Placebo, FF 100 µg/Levo 200 µg, Levo 200 µg	Sequence 6: FF 100 µg/Levo 200 µg, Placebo, Levo 200 µg
Started	3	3	2
Completed	3	3	2

Number of subjects in period 4	Sequence 7: FF 100 µg, Placebo 200 µg, FF 100 µg/Levo 200 µg	Sequence 8: FF 100 µg/Levo 200 µg, FF 100 µg, Placebo	Sequence 9: Placebo, FF 100 µg/Levo 200 µg, FF 100 µg
Started	3	3	3
Completed	3	3	3

Number of subjects in period 4	Sequence 10: FF 100 µg, FF 100 µg/Levo 200 µg, Levo 200 µg	Sequence 11: Levo 200 µg, Placebo, FF 100 µg/Levo 200 µg	Sequence 12: FF 100 µg/Levo 200 µg, Levo 200 µg, FF 100 µg
Started	6	3	6
Completed	6	3	6

Number of subjects in period 4	Sequence 13: FF 100 µg/Levo 200 µg, Levo 200 µg, Placebo	Sequence 14: FF 100 µg, FF 100 µg/Levo 200 µg, Placebo	Sequence 15: FF 100 µg/Levo 200 µg, FF 100 µg, Levo 200 µg

Started	3	3	6
Completed	3	3	6

Number of subjects in period 4	Sequence 16: FF 100 µg/Levo 200 µg, Placebo, FF 100 µg	Sequence 17: FF 100 µg, Levo 200 µg, FF 100 µg/Levo 200 µg	Sequence 18: Placebo, Levo 200 µg, FF 100 µg/Levo 200 µg
Started	3	5	3
Completed	3	5	3

Period 5

Period 5 title	Treatment Period 3 (8 days)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst

Arms

Are arms mutually exclusive?	Yes
Arm title	Sequence 1: Levo 200 µg, FF 100 µg/Levo 200 µg, placebo

Arm description:

Participants received Levo 200 µg, fluticasone furoate (FF) 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 2: Levo 200 µg, FF 100 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received Levo 200 µg, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 3: Levo 200 µg, FF 100 µg/Levo 200 µg, FF 100 µg

Arm description:

Participants received Levo 200 µg, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 4: Placebo, FF 100 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received placebo, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 5: Placebo, FF 100 µg/Levo 200 µg, Levo 200 µg

Arm description:

Participants received placebo, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 6: FF 100 µg/Levo 200 µg, Placebo, Levo 200 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, placebo and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 7: FF 100 µg, Placebo 200 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received FF 100 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo

Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 8: FF 100 µg/Levo 200 µg, FF 100 µg, Placebo

Arm description:

Participants received FF 100 µg/Levo 200 µg, FF 100 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 9: Placebo, FF 100 µg/Levo 200 µg, FF 100 µg

Arm description:

Participants received placebo, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 10: FF 100 µg, FF 100 µg/Levo 200 µg, Levo 200 µg

Arm description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution

Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 11: Levo 200 µg, Placebo, FF 100 µg/Levo 200 µg

Arm description:

Participants received Levo 200 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Arm title	Sequence 12: FF 100 µg/Levo 200 µg, Levo 200 µg, FF 100 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution

Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 13: FF 100 µg/Levo 200 µg, Levo 200 µg, Placebo

Arm description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 14: FF 100 µg, FF 100 µg/Levo 200 µg, Placebo

Arm description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 15: FF 100 µg/Levo 200 µg, FF 100 µg, Levo 200 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, FF 100 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 16: FF 100 µg/Levo 200 µg, Placebo, FF 100 µg

Arm description:

Participants received FF 100 µg/Levo 200 µg, placebo and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo

Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 17: FF 100 µg, Levo 200 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received FF 100 µg, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25 µg once daily	
Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use
Dosage and administration details: 25µg/50 µg once daily	
Arm title	Sequence 18: Placebo, Levo 200 µg, FF 100 µg/Levo 200 µg

Arm description:

Participants received placebo, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Arm type	Active comparator:Experimental:Placebo
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	levocabastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25 µg once daily

Investigational medicinal product name	Fluticasone furoate +levocabastine as fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Intranasal use

Dosage and administration details:

25µg/50 µg once daily

Number of subjects in period 5	Sequence 1: Levo 200 µg, FF 100 µg/Levo 200 µg, placebo	Sequence 2: Levo 200 µg, FF 100 µg, FF 100 µg/Levo 200 µg	Sequence 3: Levo 200 µg, FF 100 µg/Levo 200 µg, FF 100 µg
Started	3	5	6
Completed	3	5	6
Not completed	0	0	0
Adverse event, non-fatal	-	-	-

Number of subjects in period 5	Sequence 4: Placebo, FF 100 µg, FF 100 µg/Levo 200 µg	Sequence 5: Placebo, FF 100 µg/Levo 200 µg, Levo 200 µg	Sequence 6: FF 100 µg/Levo 200 µg, Placebo, Levo 200 µg
Started	3	3	2
Completed	3	3	2
Not completed	0	0	0
Adverse event, non-fatal	-	-	-

Number of subjects in period 5	Sequence 7: FF 100 µg, Placebo 200 µg, FF 100 µg/Levo 200 µg	Sequence 8: FF 100 µg/Levo 200 µg, FF 100 µg, Placebo	Sequence 9: Placebo, FF 100 µg/Levo 200 µg, FF 100 µg
Started	3	3	3

Completed	3	3	3
Not completed	0	0	0
Adverse event, non-fatal	-	-	-

Number of subjects in period 5	Sequence 10: FF 100 µg, FF 100 µg/Levo 200 µg, Levo 200 µg	Sequence 11: Levo 200 µg, Placebo, FF 100 µg/Levo 200 µg	Sequence 12: FF 100 µg/Levo 200 µg, Levo 200 µg, FF 100 µg
Started	6	3	6
Completed	6	3	6
Not completed	0	0	0
Adverse event, non-fatal	-	-	-

Number of subjects in period 5	Sequence 13: FF 100 µg/Levo 200 µg, Levo 200 µg, Placebo	Sequence 14: FF 100 µg, FF 100 µg/Levo 200 µg, Placebo	Sequence 15: FF 100 µg/Levo 200 µg, FF 100 µg, Levo 200 µg
Started	3	3	6
Completed	3	3	6
Not completed	0	0	0
Adverse event, non-fatal	-	-	-

Number of subjects in period 5	Sequence 16: FF 100 µg/Levo 200 µg, Placebo, FF 100 µg	Sequence 17: FF 100 µg, Levo 200 µg, FF 100 µg/Levo 200 µg	Sequence 18: Placebo, Levo 200 µg, FF 100 µg/Levo 200 µg
Started	3	5	3
Completed	3	4	3
Not completed	0	1	0
Adverse event, non-fatal	-	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Treatment Period 1 (8 days) (Overall)

Reporting group description:

Participants received FF 100 µg, Levo 200 µg, FF 100 µg/Levo 200 µg and placebo once daily (OD) in the morning as 2 nasal sprays (FF: 25 µg per spray, Levo: 50 µg per spray, FF/Levo: 25 µg/50 µg per spray) into each nostril for 8 days each, in a crossover design. Treatment was given in one of 18 sequences in Periods 1, 2, and 3, (with a minimum of a 14-day washout period between treatments): BCD, BAC, BCA, DAC, DCB, CDB, ADC, CAD, DCA, ACB, BDC, CBA, CBD, ACD, CAB, CDA, ABC, DBC (A, FF 100 µg; B, Levo 200 µg; C, FF 100 µg/Levo 200 µg; D, placebo). On Day 1 and Day 8 of each treatment period, participants were subjected to an allergen challenge in a Vienna Challenge Chamber (VCC) for a 4-hour period, and the assessments were conducted 12-24 hours post-dose. All participants attended a follow-up visit of 14-28 days after their last dose, and the overall duration for participation in the study (screening to follow-up) was 20 weeks.

Reporting group values	Treatment Period 1 (8 days) (Overall)	Total	
Number of subjects	71	71	
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	29.4		
standard deviation	± 8.91	-	
Gender categorical Units: Subjects			
Female	36	36	
Male	35	35	
Race Units: Subjects			
Asian - East Asian Heritage	2	2	
White - White/Caucasian/European Heritage	69	69	

End points

End points reporting groups

Reporting group title	Sequence 1: Levo 200 µg, FF 100 µg/Levo 200 µg, placebo

Reporting group description:

Participants received levocabastine (Levo) 200 micrograms (µg), fluticasone furoate (FF) 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg once daily (OD) in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 2: Levo 200 µg, FF 100 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received Levo 200 µg, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 3: Levo 200 µg, FF 100 µg/Levo 200 µg, FF 100 µg

Reporting group description:

Participants received Levo 200 µg, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 4: Placebo, FF 100 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received placebo, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 5: Placebo, FF 100 µg/Levo 200 µg, Levo 200 µg

Reporting group description:

Participants received placebo, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 6: FF 100 µg/Levo 200 µg, Placebo, Levo 200 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, placebo and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 7: FF 100 µg, Placebo 200 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received FF 100 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 8: FF 100 µg/Levo 200 µg, FF 100 µg, Placebo

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, FF 100 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were

separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 9: Placebo, FF 100 µg/Levo 200 µg, FF 100 µg

Reporting group description:

Participants received placebo, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 10: FF 100 µg, FF 100 µg/Levo 200 µg, Levo 200 µg

Reporting group description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 11: Levo 200 µg, Placebo, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received Levo 200 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 12: FF 100 µg/Levo 200 µg, Levo 200 µg, FF 100 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 13: FF 100 µg/Levo 200 µg, Levo 200 µg, Placebo

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 14: FF 100 µg, FF 100 µg/Levo 200 µg, Placebo

Reporting group description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 15: FF 100 µg/Levo 200 µg, FF 100 µg, Levo 200 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, FF 100 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 16: FF 100 µg/Levo 200 µg, Placebo, FF 100 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, placebo and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 17: FF 100 µg, Levo 200 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received FF 100 µg, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per

spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 18: Placebo, Levo 200 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received placebo, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 1: Levo 200 µg, FF 100 µg/Levo 200 µg, placebo

Reporting group description:

Participants received Levo 200 µg, FF 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 2: Levo 200 µg, FF 100 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received Levo 200 µg, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 3: Levo 200 µg, FF 100 µg/Levo 200 µg, FF 100 µg

Reporting group description:

Participants received Levo 200 µg, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 4: Placebo, FF 100 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received placebo, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 5: Placebo, FF 100 µg/Levo 200 µg, Levo 200 µg

Reporting group description:

Participants received placebo, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 6: FF 100 µg/Levo 200 µg, Placebo, Levo 200 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, placebo and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 7: FF 100 µg, Placebo 200 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received FF 100 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 8: FF 100 µg/Levo 200 µg, FF 100 µg, Placebo

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, FF 100 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 9: Placebo, FF 100 µg/Levo 200 µg, FF 100 µg

Reporting group description:

Participants received placebo, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 10: FF 100 µg, FF 100 µg/Levo 200 µg, Levo 200 µg

Reporting group description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 11: Levo 200 µg, Placebo, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received Levo 200 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 12: FF 100 µg/Levo 200 µg, Levo 200 µg, FF 100 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 13: FF 100 µg/Levo 200 µg, Levo 200 µg, Placebo

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 14: FF 100 µg, FF 100 µg/Levo 200 µg, Placebo

Reporting group description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 15: FF 100 µg/Levo 200 µg, FF 100 µg, Levo 200 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, FF 100 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 16: FF 100 µg/Levo 200 µg, Placebo, FF 100 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, placebo and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 17: FF 100 µg, Levo 200 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received FF 100 µg, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 18: Placebo, Levo 200 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received placebo, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 1: Levo 200 µg, FF 100 µg/Levo 200 µg, placebo

Reporting group description:

Participants received Levo 200 µg, FF 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 2: Levo 200 µg, FF 100 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received Levo 200 µg, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 3: Levo 200 µg, FF 100 µg/Levo 200 µg, FF 100 µg

Reporting group description:

Participants received Levo 200 µg, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 4: Placebo, FF 100 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received placebo, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 5: Placebo, FF 100 µg/Levo 200 µg, Levo 200 µg

Reporting group description:

Participants received placebo, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 6: FF 100 µg/Levo 200 µg, Placebo, Levo 200 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, placebo and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 7: FF 100 µg, Placebo 200 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received FF 100 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2

nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 8: FF 100 µg/Levo 200 µg, FF 100 µg, Placebo

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, FF 100 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 9: Placebo, FF 100 µg/Levo 200 µg, FF 100 µg

Reporting group description:

Participants received placebo, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 10: FF 100 µg, FF 100 µg/Levo 200 µg, Levo 200 µg

Reporting group description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 11: Levo 200 µg, Placebo, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received Levo 200 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 12: FF 100 µg/Levo 200 µg, Levo 200 µg, FF 100 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 13: FF 100 µg/Levo 200 µg, Levo 200 µg, Placebo

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 14: FF 100 µg, FF 100 µg/Levo 200 µg, Placebo

Reporting group description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 15: FF 100 µg/Levo 200 µg, FF 100 µg, Levo 200 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, FF 100 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 16: FF 100 µg/Levo 200 µg, Placebo, FF 100 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, placebo and FF 100 µg in Treatment Periods 1, 2, and 3,

respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 17: FF 100 µg, Levo 200 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received FF 100 µg, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 18: Placebo, Levo 200 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received placebo, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 1: Levo 200 µg, FF 100 µg/Levo 200 µg, placebo

Reporting group description:

Participants received Levo 200 µg, FF 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 2: Levo 200 µg, FF 100 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received Levo 200 µg, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 3: Levo 200 µg, FF 100 µg/Levo 200 µg, FF 100 µg

Reporting group description:

Participants received Levo 200 µg, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 4: Placebo, FF 100 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received placebo, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 5: Placebo, FF 100 µg/Levo 200 µg, Levo 200 µg

Reporting group description:

Participants received placebo, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 6: FF 100 µg/Levo 200 µg, Placebo, Levo 200 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, placebo and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 7: FF 100 µg, Placebo 200 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received FF 100 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 8: FF 100 µg/Levo 200 µg, FF 100 µg, Placebo

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, FF 100 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 9: Placebo, FF 100 µg/Levo 200 µg, FF 100 µg

Reporting group description:

Participants received placebo, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 10: FF 100 µg, FF 100 µg/Levo 200 µg, Levo 200 µg

Reporting group description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 11: Levo 200 µg, Placebo, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received Levo 200 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 12: FF 100 µg/Levo 200 µg, Levo 200 µg, FF 100 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 13: FF 100 µg/Levo 200 µg, Levo 200 µg, Placebo

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 14: FF 100 µg, FF 100 µg/Levo 200 µg, Placebo

Reporting group description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 15: FF 100 µg/Levo 200 µg, FF 100 µg, Levo 200 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, FF 100 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 16: FF 100 µg/Levo 200 µg, Placebo, FF 100 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, placebo and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 17: FF 100 µg, Levo 200 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received FF 100 µg, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 18: Placebo, Levo 200 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received placebo, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 1: Levo 200 µg, FF 100 µg/Levo 200 µg, placebo

Reporting group description:

Participants received Levo 200 µg, fluticasone furoate (FF) 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 2: Levo 200 µg, FF 100 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received Levo 200 µg, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 3: Levo 200 µg, FF 100 µg/Levo 200 µg, FF 100 µg

Reporting group description:

Participants received Levo 200 µg, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 4: Placebo, FF 100 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received placebo, FF 100 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 5: Placebo, FF 100 µg/Levo 200 µg, Levo 200 µg

Reporting group description:

Participants received placebo, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 6: FF 100 µg/Levo 200 µg, Placebo, Levo 200 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, placebo and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods

were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 7: FF 100 µg, Placebo 200 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received FF 100 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 8: FF 100 µg/Levo 200 µg, FF 100 µg, Placebo

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, FF 100 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 9: Placebo, FF 100 µg/Levo 200 µg, FF 100 µg

Reporting group description:

Participants received placebo, FF 100 µg/Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 10: FF 100 µg, FF 100 µg/Levo 200 µg, Levo 200 µg

Reporting group description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 11: Levo 200 µg, Placebo, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received Levo 200 µg, placebo and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 12: FF 100 µg/Levo 200 µg, Levo 200 µg, FF 100 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 13: FF 100 µg/Levo 200 µg, Levo 200 µg, Placebo

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 14: FF 100 µg, FF 100 µg/Levo 200 µg, Placebo

Reporting group description:

Participants received FF 100 µg, FF 100 µg/Levo 200 µg and placebo in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 15: FF 100 µg/Levo 200 µg, FF 100 µg, Levo 200 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, FF 100 µg and Levo 200 µg in Treatment Periods 1, 2, and

3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 16: FF 100 µg/Levo 200 µg, Placebo, FF 100 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg, placebo and FF 100 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) and placebo OD in the morning as 2 nasal sprays and FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 17: FF 100 µg, Levo 200 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received FF 100 µg, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Reporting group title	Sequence 18: Placebo, Levo 200 µg, FF 100 µg/Levo 200 µg

Reporting group description:

Participants received placebo, Levo 200 µg and FF 100 µg/Levo 200 µg in Treatment Periods 1, 2, and 3, respectively. Participants received the placebo OD in the morning as 2 nasal sprays and Levo 200 µg OD in the morning as 2 nasal spray (50 µg per spray) and FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) into each nostril for 8 days. The three treatment periods were separated by a washout period of 14 to 28 days.

Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received placebo OD in the morning as 2 nasal sprays in each nostril for 8 days.

Subject analysis set title	FF 100 µg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) in each nostril for 8 days.

Subject analysis set title	Levo 200 µg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received Levo 200 µg OD in the morning as 2 nasal sprays (50 µg per spray) in each nostril for 8 days.

Subject analysis set title	FF 100 µg/Levo 200 µg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) in each nostril for 8 days.

Primary: Weighted mean of the total nasal symptom score (TNSS) (0-4) hours (h) post start of allergen chamber challenge on Day 8 of each treatment period

End point title	Weighted mean of the total nasal symptom score (TNSS) (0-4) hours (h) post start of allergen chamber challenge on Day 8 of each treatment period

End point description:

The TNSS (score of 0-12) is defined as the sum of the symptom scores for the four individual components (nasal congestion, rhinorrhea, nasal itch, and sneezing, each scored on 0-3 scale [0=none, 1=mild, 2=moderate, 3=severe]). TNSS was measured at the pre-allergen chamber challenge, and then every 15 minutes from 0 to 4 hours post start of the allergen chamber challenge. In the Environmental Exposure Chamber (EEC), aerosolized allergen was administered in a sealed chamber to evaluate the efficacy of antihistamines/other treatments. Weighted mean TNSS was calculated by dividing the value of the area under the response time curve over the 0-4 hours (calculated by trapezoidal rule) by the time interval of available data.

End point type	Primary

End point timeframe:

Day 8 of each treatment period (up to 80 days)

End point values	Placebo	FF 100 µg	Levo 200 µg	FF 100 µg/Levo 200 µg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	34[1]	54[2]	53[3]	66[4]
Units: Scores on a scale				
least squares mean (confidence interval 95%)	6.03 (5.35 to 6.71)	4.189 (3.646 to 4.731)	4.5 (3.955 to 5.044)	1.933 (1.438 to 2.428)

Notes:

[1] - Pharmacodynamic (PD) Population: par. received >=1 dose investigational product and >=1 PD measure

[2] - PD Population

[3] - PD Population

[4] - PD Population

Statistical analyses

Statistical analysis title	Analysis 1
Comparison groups	FF 100 µg v FF 100 µg/Levo 200 µg
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-2.255
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.895
upper limit	-1.616

Statistical analysis title	Analysis 2
Comparison groups	Levo 200 µg v FF 100 µg/Levo 200 µg
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-2.566

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.208
upper limit	-1.925

Statistical analysis title	Analysis 3
Comparison groups	Placebo v Levo 200 µg
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0003
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-1.531
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.342
upper limit	-0.719

Statistical analysis title	Analysis 4
Comparison groups	Placebo v FF 100 µg
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-1.842
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.654
upper limit	-1.029

Statistical analysis title	Analysis 5
Comparison groups	Placebo v FF 100 µg/Levo 200 µg

Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-4.097
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.857
upper limit	-3.337

Statistical analysis title	Analysis 6
Comparison groups	FF 100 µg v Levo 200 µg
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3699
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.311
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.994
upper limit	0.372

Secondary: Weighted mean of the magnitude of symptom relief on total nasal symptom score (TNSS) (2-4) hours (h) post start of allergen chamber challenge on Day 1 of each treatment period

End point title	Weighted mean of the magnitude of symptom relief on total nasal symptom score (TNSS) (2-4) hours (h) post start of allergen chamber challenge on Day 1 of each treatment period

End point description:

Magnitude of symptom relief was assessed by calculating change from pre-dose weighted mean TNSS (2-4h) post start of the allergen chamber challenge at Day 1. The pre-dose value was the maximum of the three pre-dose measurements (1h 15 minutes (min), 1h 30 min and 1h 45 min post start of the allergen chamber challenge). The TNSS (score of 0-12) is defined as the sum of the symptom scores for the four individual components (nasal congestion, rhinorrhea, nasal itch and sneezing, each scored on 0-3 scale [0=none, 1=mild, 2=moderate, 3=severe]).

End point type	Secondary

End point timeframe:

Day 1 of each treatment period (up to 80 days)

End point values	Placebo	FF 100 µg	Levo 200 µg	FF 100 µg/Levo 200 µg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	34[5]	54[6]	53[7]	68[8]
Units: Scores on a scale				
least squares mean (confidence interval 95%)	-1.335 (-1.861 to -0.81)	-0.904 (-1.332 to -0.476)	-2.588 (-3.018 to -2.157)	-2.267 (-2.658 to -1.877)

Notes:

[5] - PD Population

[6] - PD Population

[7] - PD Population

[8] - PD Population

Statistical analyses

Statistical analysis title	Analysis 1
Comparison groups	FF 100 µg v FF 100 µg/Levo 200 µg
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-1.364
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.853
upper limit	-0.874

Statistical analysis title	Analysis 2
Comparison groups	FF 100 µg/Levo 200 µg v Levo 200 µg
Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1975
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.169
upper limit	0.809

Statistical analysis title	Analysis 3
Comparison groups	Levo 200 µg v Placebo

Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-1.252
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.87
upper limit	-0.635

Statistical analysis title	Analysis 4
Comparison groups	Placebo v FF 100 µg
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1648
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.432
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.179
upper limit	1.042

Statistical analysis title	Analysis 5
Comparison groups	Placebo v FF 100 µg/Levo 200 µg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0016
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.932
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.506
upper limit	-0.358

Statistical analysis title	Analysis 6

Comparison groups	FF 100 µg v Levo 200 µg
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	1.684
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.16
upper limit	2.208

Secondary: Weighted mean of the magnitude of symptom relief on total ocular symptom score (TOSS) (2-4) hours (h) post start of allergen chamber challenge on Day 1 of each treatment period

End point title	Weighted mean of the magnitude of symptom relief on total ocular symptom score (TOSS) (2-4) hours (h) post start of allergen chamber challenge on Day 1 of each treatment period

End point description:

Magnitude of symptom relief was assessed by calculating change from pre-dose weighted mean TOSS (2-4h) post start of the allergen chamber challenge at Day 1. The pre-dose value was the maximum of the three pre-dose measurements (1h 15 minutes (min), 1h 30 min and 1h 45 min post start of the allergen chamber challenge). The TOSS (score of 0-9) is defined as the sum of the symptom scores for the three individual components (red, itchy, and tearing eyes, each scored on 0-3 scale [0=none, 1=mild, 2=moderate, 3=severe], average of two eyes).

End point type	Secondary

End point timeframe:

Day 1 of each treatment period (up to 80 days)

End point values	Placebo	FF 100 µg	Levo 200 µg	FF 100 µg/Levo 200 µg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	34[9]	54[10]	53[11]	68[12]
Units: Scores on a scale				
least squares mean (confidence interval 95%)	-0.097 (-0.431 to 0.237)	-0.272 (-0.537 to -0.007)	-0.633 (-0.901 to -0.365)	-0.446 (-0.683 to -0.209)

Notes:

[9] - PD Population

[10] - PD Population

[11] - PD Population

[12] - PD Population

Statistical analyses

Statistical analysis title	Analysis 1
Comparison groups	FF 100 µg v FF 100 µg/Levo 200 µg

Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3052
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.174
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.508
upper limit	0.16

Statistical analysis title	Analysis 2
Comparison groups	FF 100 µg/Levo 200 µg v Levo 200 µg
Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2725
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.187
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.149
upper limit	0.523

Statistical analysis title	Analysis 3
Comparison groups	Levo 200 µg v Placebo
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0118
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.536
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.952
upper limit	-0.12

Statistical analysis title	Analysis 4

Comparison groups	FF 100 µg v Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4049
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.175
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.588
upper limit	0.239

Statistical analysis title	Analysis 5
Comparison groups	Placebo v FF 100 µg/Levo 200 µg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0793
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.349
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.739
upper limit	0.041

Statistical analysis title	Analysis 6
Comparison groups	FF 100 µg v Levo 200 µg
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0478
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.361
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.004
upper limit	0.719

Secondary: Weighted mean of the total ocular symptom score (TOSS) (0-4) hours (h) post start of allergen chamber challenge on Day 8 of each treatment period

End point title	Weighted mean of the total ocular symptom score (TOSS) (0-4) hours (h) post start of allergen chamber challenge on Day 8 of each treatment period

End point description:

The TOSS (score of 0-9) is defined as the sum of the symptom scores for the three individual components (red, itchy, and tearing eyes , each scored on 0-3 scale [0=none, 1=mild, 2=moderate, 3=severe], average of two eyes). TOSS was measured at the pre-allergen chamber challenge, and then every 15 minutes from 0 to 4 hours post start of the allergen chamber challenge. In the Environmental Exposure Chamber (EEC), aerosolized allergen was administered in a sealed chamber to evaluate the efficacy of antihistamines/other treatments. Weighted mean TOSS was calculated by dividing the value of the area under the response time curve over the 0-4 hours (calculated by trapezoidal rule) by the time interval of available data.

End point type	Secondary

End point timeframe:

Day 8 of each treatment period (up to 80 days)

End point values	Placebo	FF 100 µg	Levo 200 µg	FF 100 µg/Levo 200 µg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	34[13]	54[14]	53[15]	66[16]
Units: Scores on a scale				
least squares mean (confidence interval 95%)	1.321 (0.97 to 1.673)	0.761 (0.465 to 1.057)	0.621 (0.323 to 0.919)	0.546 (0.268 to 0.824)

Notes:

[13] - PD Population

[14] - PD Population

[15] - PD Population

[16] - PD Population

Statistical analyses

Statistical analysis title	Analysis 1
Comparison groups	FF 100 µg v FF 100 µg/Levo 200 µg
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1502
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.215
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.509
upper limit	0.079

Statistical analysis title	Analysis 2
Comparison groups	FF 100 µg/Levo 200 µg v Levo 200 µg

Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6177
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.075
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.37
upper limit	0.221

Statistical analysis title	Analysis 3
Comparison groups	Levo 200 µg v Placebo
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0004
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.701
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.08
upper limit	-0.322

Statistical analysis title	Analysis 4
Comparison groups	Placebo v FF 100 µg
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0035
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.934
upper limit	-0.187

Statistical analysis title	Analysis 5

Comparison groups	Placebo v FF 100 µg/Levo 200 µg
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.775
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.123
upper limit	-0.428

Statistical analysis title	Analysis 6
Comparison groups	FF 100 µg v Levo 200 µg
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3807
Method	Mixed Model ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.175
upper limit	0.456

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious adverse events (SAEs) and non-serious AEs were collected from the start of study treatment until the follow-up contact (up to 20 study weeks).

Adverse event reporting additional description:

SAEs and non-serious AEs were collected in members of the All Subject Population, comprised of all all participants who receive at least one dose of Investigational product. The number of occurrences for the non-serious AEs was not collected in this study; therefore, the number of occurrences has been entered as 0.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	12.0

Reporting groups

Reporting group title	Placebo

Reporting group description:

Participants received placebo OD in the morning as 2 nasal sprays in each nostril for 8 days.

Reporting group title	FF 100 µg

Reporting group description:

Participants received FF 100 µg OD in the morning as 2 nasal sprays (25 µg per spray) in each nostril for 8 days.

Reporting group title	Levo 200 µg

Reporting group description:

Participants received Levo 200 µg OD in the morning as 2 nasal sprays (50 µg per spray) in each nostril for 8 days.

Reporting group title	FF 100 µg/Levo 200 µg

Reporting group description:

Participants received FF 100 µg/Levo 200 µg OD in the morning as 2 nasal sprays (25 µg/50 µg per spray) in each nostril for 8 days.

Serious adverse events	Placebo	FF 100 µg	Levo 200 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 34 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	FF 100 µg/Levo 200 µg		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 68 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Placebo	FF 100 µg	Levo 200 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 34 (5.88%)	1 / 54 (1.85%)	1 / 53 (1.89%)
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 34 (5.88%)	1 / 54 (1.85%)	1 / 53 (1.89%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 34 (2.94%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 34 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	FF 100 µg/Levo 200 µg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 68 (4.41%)		
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences (all)	0		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences (all)	0		

Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	 1 / 68 (1.47%) 0		
Respiratory, thoracic and mediastinal disorders Oropharyngeal pain subjects affected / exposed occurrences (all)	 1 / 68 (1.47%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported