Clinical trial results:
ELABORATION OF A PATIENT-FRIENDLY TREATMENT STRATEGY WITH CAPSAICIN NASAL SPRAY IN PATIENTS WITH IDIOPATHIC RHINITIS

Summary

EudraCT number	2014-003914-10
Trial protocol	BE
Global end of trial date	31 December 2018

Results information

Result version number	v1 (current)
This version publication date	07 January 2021
First version publication date	07 January 2021

Trial information

Trial identification

Sponsor protocol code	sept2014

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02288156
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UZLeuven
Sponsor organisation address	Herestraat 49, Leuven, Belgium, 3000
Public contact	UZ Leuven, UZ Leuven, Leen.cools@uzleuven.be
Scientific contact	UZ Leuven, UZ Leuven, leen.cools@uzleuven.be

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	01 December 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 December 2018
Global end of trial reached?	Yes
Global end of trial date	31 December 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate if the two novel treatment modalities show non-inferiority compared to the current treatment modality of capsaicin nasal treatment in 120 patients with IR. The gathered data of this single center trial can be used to guide the decision on the set-up and the design of a larger multi-center trial being powered to prove non-inferiority.

Protection of trial subjects:

On the application day, the nasal mucosa was anesthetized before the first 2 applications by application of a cocaine 5% nasal spray. To ensure effective local anesthesia, an interval of 15 minutes was maintained between the application of the cocaine and the blinded nasal spray.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2015
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	Belgium: 80
Worldwide total number of subjects	80
EEA total number of subjects	80

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)	80
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were recruited in Belgium from 2015 till 2018.

Pre-assignment

Screening details:

Main inclusion criteria:
•Idiopathic rhinitis (IR) patients with at least 1 persistent (> 12w) rhinological symptoms (nasal discharge, sneezing, nasal congestion) for an average of at least 1 h per day,
•IR patients with a total nasal symptoms score (TNS) of 5 or more on a visual analogue scale (VAS).
•Age > 18 and < 60 years.

Period 1

Period 1 title	Overall period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	0,1mM Capsaïcin / Placebo

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Capsaicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use

Dosage and administration details:

Patient is treated with 0,1mM capsaicin, 5 applications on 1 day at 1-hour intervals.
per application: 2 puffs in each nostril, 0.4mL/puff.
4 weeks thereafter, the patient is treated daily with placebo

Arm title	Placebo / 0,01mM Capsaicin

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Capsaicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use

Dosage and administration details:

Patient is treated with placebo, 5 applications on 1 day at 1-hour intervals.
per application: 2 puffs in each nostril, 0.4mL/puff.
4 weeks thereafter, the patient is treated daily with 0,01mM Capsaicin

Arm title	Placebo / 0,001mM Capsaicin

Arm description: -

Arm type	Experimental

Investigational medicinal product name	Capsaicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use

Dosage and administration details:

Patient is treated with placebo, 5 applications on 1 day at 1-hour intervals.
per application: 2 puffs in each nostril, 0.4mL/puff.
4 weeks thereafter, the patient is treated daily with 0,001mM Capsaicin

Arm title	Placebo / Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use

Dosage and administration details:

Patient is treated with placebo, 5 applications on 1 day at 1-hour intervals.
per application: 2 puffs in each nostril, 0.4mL/puff.
4 weeks thereafter, the patient is treated daily with placebo

Number of subjects in period 1	0,1mM Capsaïcin / Placebo	Placebo / 0,01mM Capsaicin	Placebo / 0,001mM Capsaicin
Started	20	20	20
Completed	16	16	18
Not completed	4	4	2
Lost to follow-up	2	3	2
Protocol deviation	2	1	-
Lack of efficacy	-	-	-

Number of subjects in period 1	Placebo / Placebo
Started	20
Completed	18
Not completed	2
Lost to follow-up	1
Protocol deviation	-
Lack of efficacy	1

Baseline characteristics

Reporting groups	
Reporting group title	0,1mM Capsaïcin / Placebo
Reporting group description: -	
Reporting group title	Placebo / 0,01mM Capsaicin
Reporting group description: -	
Reporting group title	Placebo / 0,001mM Capsaicin
Reporting group description: -	
Reporting group title	Placebo / Placebo
Reporting group description: -	

Reporting group values	0,1mM Capsaïcin / Placebo	Placebo / 0,01mM Capsaicin	Placebo / 0,001mM Capsaicin
Number of subjects	20	20	20
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
Units: years			
arithmetic mean	50	45	48
standard deviation	± 14	± 10	± 14
Gender categorical			
Units: Subjects			
Female	11	9	10
Male	9	11	10

Reporting group values	Placebo / Placebo	Total	
Number of subjects	20	80	
Age categorical			
Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	

85 years and over		0	

Age continuous Units: years			
arithmetic mean	45		
standard deviation	± 15	-	
Gender categorical Units: Subjects			
Female	11	41	
Male	9	39	

End points

End points reporting groups

Reporting group title	0,1mM Capsaïcin / Placebo
Reporting group description: -	
Reporting group title	Placebo / 0,01mM Capsaicin
Reporting group description: -	
Reporting group title	Placebo / 0,001mM Capsaicin
Reporting group description: -	
Reporting group title	Placebo / Placebo
Reporting group description: -	

Primary: VAS major nasal symptom at week 4

End point title	VAS major nasal symptom at week 4
End point description:	
Comparison of VAS for major nasal symptom at week 4 in all treatments modalities. The region of equivalence of the compared treatment modalities is defined as a difference in VAS of less than 1.	
End point type	Primary
End point timeframe:	
Week 4 after treatment	

End point values	0,1mM Capsaïcin / Placebo	Placebo / 0,01mM	Placebo / 0,001mM	Placebo / Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	18	18
Units: VAS score				
arithmetic mean (standard deviation)	3.66 (± 2.78)	4.29 (± 2.92)	4.49 (± 2.93)	5.6 (± 1.67)

Statistical analyses

Statistical analysis title	Compairison of VAS values between different groups
Statistical analysis description:	
The VAS major nasal symptom was compared at 4 weeks post treatment between the dfferent treatment groups	
Comparison groups	0,1mM Capsaïcin / Placebo v Placebo / 0,01mM Capsaicin v Placebo / 0,001mM Capsaicin v Placebo / Placebo
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	≤ 0.05
Method	ANOVA

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From signing informed consent till end of study	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	23.1

Reporting groups	
Reporting group title	0,1mM Capsaïcin / Placebo
Reporting group description: -	
Reporting group title	Placebo / 0,01mM Capsaicin
Reporting group description: -	
Reporting group title	Placebo / 0,001mM Capsaicin
Reporting group description: -	
Reporting group title	Placebo / Placebo
Reporting group description: -	

Serious adverse events	0,1mM Capsaïcin / Placebo	Placebo / 0,01mM Capsaicin	Placebo / 0,001mM Capsaicin
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	Placebo / Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 18 (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	0,1mM Capsaïcin / Placebo	Placebo / 0,01mM Capsaicin	Placebo / 0,001mM Capsaicin
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 16 (62.50%)	8 / 16 (50.00%)	14 / 18 (77.78%)
Surgical and medical procedures			

Eyelid operation			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Head discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Loss of consciousness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Mite allergy			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Eye irritation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Eye pruritus			

subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Food poisoning			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 16 (6.25%)	2 / 16 (12.50%)	0 / 18 (0.00%)
occurrences (all)	1	2	0
Epistaxis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 16 (0.00%)	3 / 16 (18.75%)	1 / 18 (5.56%)
occurrences (all)	0	3	1
Nasal crusting			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Nasal discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	2 / 16 (12.50%)	2 / 16 (12.50%)	1 / 18 (5.56%)
occurrences (all)	2	2	1
Sneezing			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Throat clearing			

subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Upper-airway cough syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 16 (12.50%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Pain in extremity			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Cystitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Ear infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Eye infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Gastroenteritis viral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	1 / 16 (6.25%)	1 / 16 (6.25%)	3 / 18 (16.67%)
occurrences (all)	1	1	3
Laryngitis			

subjects affected / exposed	1 / 16 (6.25%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	1	2	0
Nasopharyngitis			
subjects affected / exposed	7 / 16 (43.75%)	5 / 16 (31.25%)	8 / 18 (44.44%)
occurrences (all)	11	9	9
Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	3 / 18 (16.67%)
occurrences (all)	2	0	5
Tonsillitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	1	0

Non-serious adverse events	Placebo / Placebo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 18 (66.67%)		
Surgical and medical procedures			
Eyelid operation			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Head discomfort			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Headache			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	2		
Loss of consciousness			

subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Malaise			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Immune system disorders			
Mite allergy			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Eye disorders			
Eye irritation			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Eye pruritus			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Food poisoning			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Epistaxis			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Nasal congestion			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Nasal crusting			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Nasal discomfort			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Oropharyngeal pain			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	2		
Rhinorrhoea			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Sneezing			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Throat clearing			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Upper-airway cough syndrome			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Back pain			

subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Cystitis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Ear infection			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Eye infection			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Gastroenteritis viral			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Gastrointestinal infection			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Influenza			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Laryngitis			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	6 / 18 (33.33%)		
occurrences (all)	9		
Pneumonia			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Respiratory tract infection			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		

Rhinitis			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Sinusitis			
subjects affected / exposed	2 / 18 (11.11%)		
occurrences (all)	2		
Tonsillitis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	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