Clinical trial results:
Open label two treatment half-side comparative study to analyse difference in nasal bioavailability between MP29-02 and fluticasone propionate.

Summary

EudraCT number	2015-002865-40
Trial protocol	BE
Global end of trial date	25 February 2019

Results information

Result version number	v1 (current)
This version publication date	25 July 2021
First version publication date	25 July 2021
Summary attachment (see zip file)	Cancelled Before Active Statement (2015-002865-40.docx)

Trial information

Trial identification

Sponsor protocol code	BIODYMF

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Ghent University Hospital
Sponsor organisation address	Corneel Heymanslaan 10, Ghent, Belgium, 9000
Public contact	Hiruz CTU, Ghent University Hospital, +32 93320500, hiruz.ctu@uzgent.be
Scientific contact	Hiruz CTU, Ghent University Hospital, +32 93320500, hiruz.ctu@uzgent.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	25 February 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 February 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of this study is to investigate and to compare the bioavailability of MP29-02 and fluticasone propionate in nasal tissue after nasal application.

Protection of trial subjects:

Ethics review and approval, informed consent, supportive care and routine monitoring.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 October 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: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

99999 is "Not applicable" value or 0 participants.

Pre-assignment

Screening details:

Inclusion criteria:
- Male and female patients
- Age: 18 – 70 years (included)
- Subjects who need to undergo septoplasty, septorhinoplasty or functional endoscopic sinus surgery unrelated to this study
- Willing and able to provide informed consent

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	Flixonase aqua

Arm description:

1 dose each in a different nostril administered via single dose nasal spray.

Arm type	Active comparator
Investigational medicinal product name	Fluticasone propionate (flixonase aqua)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, suspension
Routes of administration	Nasal use

Dosage and administration details:

Each spray delivers 50 mcg of fluticasone propionate.

Arm title	MP29-02

Arm description:

1 dose each in a different nostril administered via single dose nasal spray.

Arm type	Experimental
Investigational medicinal product name	MP29-02
Investigational medicinal product code	
Other name	Dymista
Pharmaceutical forms	Nasal spray
Routes of administration	Local use , Nasal use

Dosage and administration details:

Total dose: 0,14 g gram(s). Nasal use.

Number of subjects in period 1	Flixonase aqua	MP29-02
Started	99999	99999
Completed	99999	99999

Baseline characteristics

Reporting groups	
Reporting group title	Flixonase aqua
Reporting group description:	
1 dose each in a different nostril administered via single dose nasal spray.	
Reporting group title	MP29-02
Reporting group description:	
1 dose each in a different nostril administered via single dose nasal spray.	

Reporting group values	Flixonase aqua	MP29-02	Total
Number of subjects	99999	99999	99999
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	99999	99999	99999
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	99999	99999	99999
Male	0	0	0

End points

End points reporting groups

Reporting group title	Flixonase aqua
Reporting group description:	
1 dose each in a different nostril administered via single dose nasal spray.	
Reporting group title	MP29-02
Reporting group description:	
1 dose each in a different nostril administered via single dose nasal spray.	

Primary: To determine the bioavailability of MP29-02 in comparison with commercially available fluticasone propionate in human nasal mucosa.

End point title	To determine the bioavailability of MP29-02 in comparison with commercially available fluticasone propionate in human nasal mucosa.[1]
End point description:	
99999 is "not applicable" value or 0 participants.	
End point type	Primary
End point timeframe:	
Approximately 1 hour after administration (during surgery).	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis available.

End point values	Flixonase aqua	MP29-02		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	99999[2]	99999[3]		
Units: fraction				
number (not applicable)	99999	99999		

Notes:

[2] - No patients enrolled in the trial.

[3] - No patients enrolled in the trial.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
Overall study	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	24

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

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No non-serious adverse events were recorded for the participating patients.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 November 2016	Amendment to information in the CT application form, amendment to the protocol, changes in conduct or management of the trial, : Some issues were clarified in the protocol, as well as the description of the IMP, previously indicated as flixonase aqua, was changed to a more broad description (without using 1 specific brand) as the use of the active substance fluticasone propionate.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

No patients have been enrolled. The trial was never initiated.

Notes: