Clinical trial results:
Intestinal disposition of budesonide in healthy volunteers

Summary

EudraCT number	2019-003271-19
Trial protocol	BE
Global end of trial date	31 January 2021

Results information

Result version number	v1 (current)
This version publication date	27 September 2024
First version publication date	27 September 2024

Trial information

Trial identification

Sponsor protocol code	DDD19IBDBUD

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	KU Leuven Drug Delivery and Disposition
Sponsor organisation address	ON2 / Herestraat 49, Leuven, Belgium, 3000
Public contact	Drug Delivery & Disposition - Patrick Augustijns, KU Leuven, patrick.augustijns@kuleuven.be
Scientific contact	Drug Delivery & Disposition - Patrick Augustijns, KU Leuven, patrick.augustijns@kuleuven.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	12 February 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 January 2021
Global end of trial reached?	Yes
Global end of trial date	31 January 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To study the disposition and bioavailability of Budesonide at the level of the colon and blood

Protection of trial subjects:

xylocaine spray/gel during positioning and removal of nasogastric catheter

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 February 2020
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: 5
Worldwide total number of subjects	5
EEA total number of subjects	5

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)	5
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

healthy volunteers

Pre-assignment

Screening details:

Candidate participants were screened for in- and exclusion criteria.

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	Entocort budesonide

Arm description:

Entocort budesonide

Arm type	Experimental
Investigational medicinal product name	budesonide (Entocort)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Entocort budesonide 3 mg administered with 240 ml water in fasted state

Arm title	Budenofalk budesonide

Arm description:

Budenofalk budesonide

Arm type	Experimental
Investigational medicinal product name	budesonide (Budenofalk)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Budenofalk budesonide 3 mg administered with 240 ml water in fasted state

Arm title	Ferring budesonide

Arm description:

Ferring budesonide

Arm type	Experimental
Investigational medicinal product name	budesonide (Ferring)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Ferring budesonide 9 mg administered with 240 ml water in fasted state

Arm title	budesonide + nexiam

Arm description:

Budenofalk (3 mg budesonide) following 3-day Nexiam treatment (1x 40 mg esomeprazole / day)

Arm type	Experimental
Investigational medicinal product name	budesonide (Budenofalk)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Budenofalk budesonide 3 mg administered with 240 ml water in fasted state

Investigational medicinal product name	nexiam
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

For the PPI test condition, subjects were asked to take one tablet of Nexiam® 40 mg once-daily (before breakfast), starting two days prior to the day of the trial (i.e., final dose taken in the morning of the day of the trial).

Number of subjects in period 1	Entocort budesonide	Budenofalk budesonide	Ferring budesonide
Started	5	5	5
Completed	5	5	5

Number of subjects in period 1	budesonide + nexiam
Started	5
Completed	5

Baseline characteristics

Reporting groups	
Reporting group title	Entocort budesonide
Reporting group description: Entocort budesonide	
Reporting group title	Budenofalk budesonide
Reporting group description: Budenofalk budesonide	
Reporting group title	Ferring budesonide
Reporting group description: Ferring budesonide	
Reporting group title	budesonide + nexiam
Reporting group description: Budenofalk (3 mg budesonide) following 3-day Nexiam treatment (1x 40 mg esomeprazole / day)	

Reporting group values	Entocort budesonide	Budenofalk budesonide	Ferring budesonide
Number of subjects	5	5	5
Age categorical Units: Subjects			
Adults (18-64 years)	5	5	5
Age continuous Units: years			
median	23	23	23
full range (min-max)	21 to 25	21 to 25	21 to 25
Gender categorical Units: Subjects			
Female	1	1	1
Male	4	4	4

Reporting group values	budesonide + nexiam	Total	
Number of subjects	5	5	
Age categorical Units: Subjects			
Adults (18-64 years)	5	5	
Age continuous Units: years			
median	23		
full range (min-max)	21 to 25	-	
Gender categorical Units: Subjects			
Female	1	1	
Male	4	4	

End points

End points reporting groups

Reporting group title	Entocort budesonide
Reporting group description: Entocort budesonide	
Reporting group title	Budenofalk budesonide
Reporting group description: Budenofalk budesonide	
Reporting group title	Ferring budesonide
Reporting group description: Ferring budesonide	
Reporting group title	budesonide + nexiam
Reporting group description: Budenofalk (3 mg budesonide) following 3-day Nexiam treatment (1x 40 mg esomeprazole / day)	

Primary: Systemic exposure to budesonide

End point title	Systemic exposure to budesonide[1]
End point description:	
End point type	Primary
End point timeframe: 0-24 h post drug intake	

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: This study was designed as exploratory, i.e. without the intention to formally test hypotheses. As such, the data obtained are descriptive in nature and do not allow statistical comparison.

End point values	Entocort budesonide	Budenofalk budesonide	Ferring budesonide	budesonide + nexiam
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	5	5
Units: ng/mL*h				
arithmetic mean (full range (min-max))	6.74 (3.78 to 8.76)	6.17 (4.31 to 13.05)	7.76 (5.37 to 15.54)	4.15 (2.41 to 8.82)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: From first visit of first subject till last visit of last subject.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	23

Frequency threshold for reporting non-serious adverse events: 5 %

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 adverse events happened during the study.

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

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

This study was designed as exploratory, i.e. without the intention to formally test hypotheses. As such, the data obtained are descriptive in nature and do not allow statistical comparison.

Notes: