



## Clinical trial results: Gastrointestinal behaviour of mesalazine in healthy volunteers Summary

EudraCT number	2019-001009-26
Trial protocol	BE
Global end of trial date	25 March 2021

### Results information

Result version number	v1 (current)
This version publication date	07 February 2023
First version publication date	07 February 2023

### Trial information

#### Trial identification

Sponsor protocol code	DDD19GISAM
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Clinical Trial Center UZ Leuven: S62903

Notes:

#### Sponsors

Sponsor organisation name	KU Leuven
Sponsor organisation address	Herestraat 49, Leuven, Belgium, 3000
Public contact	Drug Delivery and Disposition, KU Leuven, +32 16329943, patrick.augustijns@kuleuven.be
Scientific contact	Drug Delivery and Disposition, KU Leuven, +32 16329943, 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	26 March 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 March 2021
Global end of trial reached?	Yes
Global end of trial date	25 March 2021
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The general aim is to assess the pharmacokinetic disposition of mesalazine in the upper gastrointestinal tract of healthy volunteers. To this end, the present study pursues the sampling of gastric and intestinal fluids, and blood after oral delivery of a single dose of mesalazine, in addition of Nexiam (PPI) in fasted or fed state. Hereby, four conditions will be evaluated using a cross-over design to assess differences in release of mesalazine formulations.

Protection of trial subjects:

Healthy volunteers

xylocaine spray/gel during positioning and removal of nasogastric catheter

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 November 2019
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 fulfilling inclusion/exclusion criteria were recruited

### Pre-assignment

Screening details:

Exclusion criteria for participation

included illness at the time of the study, allergy for salicylic derivatives, medication use (excluding contraceptives), history of acute/chronic GI disease(s), and pregnancy.

### Period 1

Period 1 title	overall period
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

### Arms

Are arms mutually exclusive?	No
<b>Arm title</b>	pentasa (500 mg mesalazine)

Arm description:

1. oral intake of one Pentasa tablet (500 mg mesalazine)

Arm type	control condition
Investigational medicinal product name	pentasa (500 mg mesalazine)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Prolonged-release tablet
Routes of administration	Oral use

Dosage and administration details:

on the test day at the University Hospitals Leuven volunteers ingested one tablet of Pentasa with 240 mL of tap water

<b>Arm title</b>	claversal (500 mg mesalazine)
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Arm description:

2. oral intake of one Claversal tablet (500 mg mesalazine)

Arm type	control condition
Investigational medicinal product name	claversal (500 mg mesalazine)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

on the test day at the University Hospitals Leuven volunteers ingested one tablet of Claversal with 240 mL of tap water (t = 0)

<b>Arm title</b>	PPI + pentasa (mesalazine 500 mg)
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Arm description:

3. oral intake of one Pentasa tablet (500 mg mesalazine) following PPI pre-treatment

Arm type	Experimental
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Investigational medicinal product name	esomeprazole
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

For the PPI conditions, volunteers were pre-treated with a once-daily dose of Nexiam (40 mg esomeprazole, corresponding to the recommended daily dose) in the morning, starting two days prior to the test day; a third and final dose was taken in the morning of the test day.

Investigational medicinal product name	pentasa (500 mg mesalazine)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Prolonged-release tablet
Routes of administration	Oral use

Dosage and administration details:

on the test day at the University Hospitals Leuven volunteers ingested one tablet of Pentasa with 240 mL of tap water

<b>Arm title</b>	PPI + claversal (500 mg mesalazine)
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Arm description:

4. oral intake of one Claversal tablet (500 mg mesalazine) following PPI pre-treatment

Arm type	Experimental
Investigational medicinal product name	claversal (500 mg mesalazine)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

on the test day at the University Hospitals Leuven volunteers ingested one tablet of Claversal with 240 mL of tap water (t = 0)

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

Dosage and administration details:

For the PPI conditions, volunteers were pre-treated with a once-daily dose of Nexiam (40 mg esomeprazole, corresponding to the recommended daily dose) in the morning, starting two days prior to the test day; a third and final dose was taken in the morning of the test day.

<b>Number of subjects in period 1</b>	pentasa (500 mg mesalazine)	claversal (500 mg mesalazine)	PPI + pentasa (mesalazine 500 mg)
	Started	5	
Completed	5	5	5

<b>Number of subjects in period 1</b>	PPI + claversal (500 mg mesalazine)
Started	5

Completed	5
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## Baseline characteristics

### Reporting groups

Reporting group title	overall period
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Reporting group description: -

Reporting group values	overall period	Total	
Number of subjects	5	5	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	5	5	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Units: years			
median	24		
full range (min-max)	22 to 26	-	
Gender categorical			
Units: Subjects			
Female	3	3	
Male	2	2	

## End points

### End points reporting groups

Reporting group title	pentasa (500 mg mesalazine)
Reporting group description: 1. oral intake of one Pentasa tablet (500 mg mesalazine)	
Reporting group title	claversal (500 mg mesalazine)
Reporting group description: 2. oral intake of one Claversal tablet (500 mg mesalazine)	
Reporting group title	PPI + pentasa (mesalazine 500 mg)
Reporting group description: 3. oral intake of one Pentasa tablet (500 mg mesalazine) following PPI pre-treatment	
Reporting group title	PPI + claversal (500 mg mesalazine)
Reporting group description: 4. oral intake of one Claversal tablet (500 mg mesalazine) following PPI pre-treatment	

### Primary: not applicable

End point title	not applicable <sup>[1]</sup>
End point description: Since we only conduct observational tests in a few volunteers, statistical and hypothesis testing is not applicable.	
End point type	Primary
End point timeframe: not applicable	

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: Since we only conduct observational tests in a few volunteers, statistical and hypothesis testing is not applicable.

End point values	pentasa (500 mg mesalazine)	claversal (500 mg mesalazine)	PPI + pentasa (mesalazine 500 mg)	PPI + claversal (500 mg mesalazine)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	5	5
Units: not applicable	5	5	5	5

### Statistical analyses

No statistical analyses for this end point

## Adverse events

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### Adverse events information<sup>[1]</sup>

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Timeframe for reporting adverse events:

For each individual, corresponds to timeframe of study participation (from signing of informed consent until last visit).

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	MedDRA
Dictionary version	23

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

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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: there were no adverse events during the trial

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 September 2020	"The replacement of a double-lumen catheter by a jejunal catheter. This allows to aspirate further down the gastrointestinal tract (proximal jejunum). Restart study after Covid19 measures."

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported

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### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/35339635>