Clinical trial results:
The role of mast cells on duodenal permeability after duodenal acid perfusion in healthy volunteers

Summary

EudraCT number	2015-000244-42
Trial protocol	BE
Global end of trial date	13 December 2016

Results information

Result version number	v1 (current)
This version publication date	10 April 2025
First version publication date	10 April 2025

Trial information

Trial identification

Sponsor protocol code	acid_permeability_healthyvolunteers

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	UZLeuven / KULeuven / TARGID
Sponsor organisation address	herestraat 49, Leuven, Belgium, 3000
Public contact	Jan Tack, UZLeuven / KULeuven / TARGID, jan.tack@kuleuven.be
Scientific contact	Jan Tack, UZLeuven / KULeuven / TARGID, jan.tack@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	13 December 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 December 2016
Global end of trial reached?	Yes
Global end of trial date	13 December 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the effect of mast cell inhibition on duodenal mucosal integrity of healthy volunteers after acid infusion in the duodenum

Protection of trial subjects:

healthy volunteers

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 April 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: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	20
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Healthy volunteers were recruited from a mailing list

Pre-assignment

Screening details:

exclusion of gastrointestinal symptoms
no history of gastrointestinal disease
no regular use of medication besides oral contraceptives,
no type 1 or 2 diabetes
no first-degree family members with type 1 diabetes, celiac disease or inflammatory bowel disease
no first-degree family members with type 1 diabetes, celiac disease or IBD

Period 1

Period 1 title	2 week mast cell stabilization or plac
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Data analyst

Arms

Are arms mutually exclusive?	No
Arm title	disodiumcromoglycate

Arm description:

intake of disodiumcromoglycate
(DSCG; Nalcrom, Italchimici SpA, Rome, Italy), a mast cell stabilizer, 200 mg qid for 2 weeks before the acid perfusion study

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

Dosage and administration details:

intake of oral disodiumcromoglycate (DSCG; Nalcrom, Italchimici SpA, Rome, Italy), a mast cell stabilizer, 200 mg qid for 2 weeks before study day with acid perfusion study

Arm title	placebo

Arm description:

intake of oral placebo (190 mg mannitol) qid during 2 weeks before the acid perfusion study

Arm type	Placebo
Investigational medicinal product name	placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Oral intake of placebo capsule (190 mg mannitol) qid for 2 weeks before the acid perfusion study day

Number of subjects in period 1	disodiumcromoglycate	placebo
Started	10	10
Completed	10	10

Period 2	
Period 2 title	part 1 saline/acid perfusion
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Data analyst

Arms	
Are arms mutually exclusive?	Yes
Arm title	saline

Arm description:

Afer a stabilization period of 20 min, one investigator started the infusion of saline in the duodenum at a rate of 5 mL min−1 during 30 min, in a randomized, cross-over manner

Arm type	Placebo
Investigational medicinal product name	saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for infusion
Routes of administration	Infusion

Dosage and administration details:

an assembly including a pH electrode with an antimony pH sensor and a thin infusion tube (2 mm diameter)
was introduced transnasally and positioned in the second portion of the duodenum afer an overnight fast. Infusion of saline in the duodenum at a rate of 5 mL min−1 during 30 min

Arm title	acid infusion

Arm description:

Afer a stabilization period of 20 min, one investigator started the infusion of f 0.1 N HCl (acid) in the duodenum at a rate of 5 mL min−1 during 30 min, in a randomized, cross-over manner

Arm type	Active comparator
Investigational medicinal product name	0.1 N HCl (acid)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Other use

Dosage and administration details:

an assembly including a pH electrode with an antimony pH sensor and a thin infusion tube (2 mm diameter)
was introduced transnasally and positioned in the second portion of the duodenum afer an overnight fast. Infusion of 0.1 N HCl (acid) in the duodenum at a rate of 5 mL min−1 during 30 min

Number of subjects in period 2	saline	acid infusion
Started	10	10
Completed	10	10

Period 3	
Period 3 title	overal trial
Is this the baseline period?	Yes[1]
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Data analyst

Arms

Arm title	overal trial
Arm description: -	
Arm type	overal trial subjects
Investigational medicinal product name	disodiumcromoglycate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: intake of oral disodiumcromoglycate (DSCG; Nalcrom, Italchimici SpA, Rome, Italy), a mast cell stabilizer, 200 mg qid for 2 weeks before study day with acid perfusion study	
Investigational medicinal product name	placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: Oral intake of placebo capsule (190 mg mannitol) qid for 2 weeks before the acid perfusion study day	
Investigational medicinal product name	saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for infusion
Routes of administration	Infusion
Dosage and administration details: an assembly including a pH electrode with an antimony pH sensor and a thin infusion tube (2 mm diameter) was introduced transnasally and positioned in the second portion of the duodenum afer an overnight fast. Infusion of saline in the duodenum at a rate of 5 mL min−1 during 30 min	
Investigational medicinal product name	0.1 N HCl (acid)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Other use

Dosage and administration details:

an assembly including a pH electrode with an antimony pH sensor and a thin infusion tube (2 mm diameter)
was introduced transnasally and positioned in the second portion of the duodenum afer an overnight fast. Infusion of 0.1 N HCl (acid) in the duodenum at a rate of 5 mL min−1 during 30 min

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: The study was divided into 2 parts with each 10 healthy volunteers. In total there were 20 participants. Period 3 was made as the overall study to be able to set the baseline characteristics of all 20 participants together.

Number of subjects in period 3	overal trial
Started	20
Completed	20

Baseline characteristics

Reporting groups	
Reporting group title	overal trial
Reporting group description: full group: part 1 + part 2	

Reporting group values	overal trial	Total	
Number of subjects	20	20	
Age categorical Units: Subjects			
Adults (18-64 years)	20	20	
Age continuous Units: years			
arithmetic mean	28.9		
standard deviation	± 8	-	
Gender categorical Units: Subjects			
Female	14	14	
Male	6	6	

End points

End points reporting groups

Reporting group title	disodiumcromoglycate
Reporting group description:	
intake of disodiumcromoglycate (DSCG; Nalcrom, Italchimici SpA, Rome, Italy), a mast cell stabilizer, 200 mg qid for 2 weeks before the acid perfusion study	

Reporting group title	placebo
Reporting group description:	
intake of oral placebo (190 mg mannitol) qid during 2 weeks before the acid perfusion study	

Reporting group title	saline
Reporting group description:	
Afer a stabilization period of 20 min, one investigator started the infusion of saline in the duodenum at a rate of 5 mL min−1 during 30 min, in a randomized, cross-over manner	

Reporting group title	acid infusion
Reporting group description:	
Afer a stabilization period of 20 min, one investigator started the infusion of f 0.1 N HCl (acid) in the duodenum at a rate of 5 mL min−1 during 30 min, in a randomized, cross-over manner	

Reporting group title	overal trial
Reporting group description: -	

Primary: Intragastric pressure

End point title	Intragastric pressure
End point description:	

End point type	Primary
End point timeframe:	
A high-resolution manometry (HRM) catheter was inserted . After a stabilization period of 20 min, infusion of 0.1 N HCl (acid) or saline was started in the duodenum at a rate of 5 mL min−1 during 30 min, in a randomized, cross-over manner.	

End point values	disodiumcromoglycate	placebo	saline	acid infusion
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	10	10	10
Units: mmHg				
least squares mean (standard deviation)	-39.8 (± 17.8)	-36.7 (± 9.1)	9.6 (± 8.1)	-52.4 (± 13.2)

Statistical analyses

Statistical analysis title	IGP infusion vs saline
Comparison groups	saline v acid infusion

Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	t-test, 1-sided

Primary: Intragastric pressure

End point title	Intragastric pressure

End point description:

End point type	Primary

End point timeframe:

a high-resolution manometry (HRM) catheter) was inserted through the nose and positioned in the gastric fundus. Afer a stabilization period of 20 min infusion of 0.1 N HCl (acid) or saline in the duodenum at a rate of 5 mL min−1 during 30 min.

End point values	disodiumcromoglycate	placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: mmHg				
median (standard deviation)	-39.8 (± 17.8)	-36.7 (± 9.1)		

Statistical analyses

Statistical analysis title	intragastric pressure
Comparison groups	placebo v disodiumcromoglycate
Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.86
Method	t-test, 1-sided

Adverse events

Adverse events information[1]	
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

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: there were no AE during this trial

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/33060783