Clinical trial results:
Effect of Proton Pump Inhibitors on the duodenal microbiome in healthy volunteers

Summary

EudraCT number	2017-004248-39
Trial protocol	BE
Global end of trial date	22 September 2020

Results information

Result version number	v1 (current)
This version publication date	05 December 2020
First version publication date	05 December 2020
Summary attachment (see zip file)	Summary (Summary.docx)

Trial information

Trial identification

Sponsor protocol code	PPI-microbiome

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03545243
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	KU Leuven
Sponsor organisation address	Herestraat, 49, Leuven, Belgium, 3000
Public contact	TARGID, TARGID, KU Leuven, +32 16372093, lucas.wauters@kuleuven.be
Scientific contact	TARGID, TARGID, KU Leuven, 0484119682 16372093, lucas.wauters@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	22 September 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 September 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the effect of Proton Pump Inhibitors (PPI) on the duodenal, oral and fecal microbiota composition in healthy volunteers

Protection of trial subjects:

local and optional IV sedation with endoscopy
local sedation and radioprotection with nasoduodenal tube

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 February 2018
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: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	30
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

All data were collected at KU Leuven and University Hospitals Leuven (Leuven, Belgium) between April 2018 - April 2020

Pre-assignment

Screening details:

All subjects were female or male, aged 18 to 64 years old, with no active psychiatric, atopic, inflammatory or metabolic conditions.

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

open

Arms

Arm title	Healthy volunteers

Arm description:

Study procedures were performed before and after (1) start PPI-therapy (pantoprazole 40mg OD for 4 weeks)

Arm type	Experimental
Investigational medicinal product name	Pantomed
Investigational medicinal product code	A02BC02
Other name	pantoprazole
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

40mg once daily for 4 weeks

Number of subjects in period 1	Healthy volunteers
Started	30
Completed	30

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	30	30	
Age categorical			
0			
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)	30	30	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
age			
Units: years			
arithmetic mean	30		
standard deviation	± 30	-	
Gender categorical			
0			
Units: Subjects			
Female	21	21	
Male	9	9	

End points

End points reporting groups

Reporting group title	Healthy volunteers
Reporting group description:	
Study procedures were performed before and after (1) start PPI-therapy (pantoprazole 40mg OD for 4 weeks)	

Primary: duodenal eosinophils

End point title	duodenal eosinophils[1]
End point description:	
duodenal eosinophil counts	
End point type	Primary
End point timeframe:	
overall trial	

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: Please refer to Charts for statistical data section regarding within-group analysis

End point values	Healthy volunteers			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: per mm square				
arithmetic mean (standard error)	229.22 (± 21.01)			

Attachments (see zip file)	HV/within-group HV.docx

Statistical analyses

No statistical analyses for this end point

Secondary: Symptoms

End point title	Symptoms
End point description:	
0	
End point type	Secondary
End point timeframe:	
overall trial	

End point values	Healthy volunteers			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: PAGI-SYM				
arithmetic mean (standard error)	0.19 (± 0.05)			

Attachments (see zip file)	HV/within-group HV.docx

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: overall trial	
Adverse event reporting additional description: 0	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	4

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 serious adverse event was observed with pantomed in healthy volunteers

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.

NA

Notes: