



Clinical trial results:

Effect of Proton Pump Inhibitors on the duodenal microbiome in healthy volunteers

Summary

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|--------------------------|-------------------|
| 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 | |

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|----------------------------------|--------------------|--|--|--|
| 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 (\pm 0.05) | | | |

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|-----------------------------------|-------------------------|
| 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

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|-----------------|-------|
| 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.

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| NA |
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Notes: