Clinical trial results:
insulin resistance, obesity and gastrointestinal bacteria

Summary

EudraCT number	2015-000197-35
Trial protocol	IT
Global end of trial date	26 April 2023

Results information

Result version number	v1 (current)
This version publication date	05 February 2025
First version publication date	05 February 2025

Trial information

Trial identification

Sponsor protocol code	IR-HP-14-01

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	IRCCS Azienda Ospedaliero-Universitaria di Bologna
Sponsor organisation address	Via Albertoni, 15, Bologna, Italy, 40138, Bologna, Italy,
Public contact	Federico Perna, IRCCS Azienda Ospedaliero-Universitaria di Bologna, +39 3471730707, federicoperna73@gmail.com
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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	19 December 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 December 2018
Global end of trial reached?	Yes
Global end of trial date	26 April 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study was to evaluate the effects of the eradication of Helicobacter pylori, in overweight / obese subjects, using as a pharmacological treatment a 10-day standard therapy (40 mg of pantoprazole, 500 mg of clarithromycin, and 1 g of amoxicillin, each administered twice daily) on insulin resistance, with a interventional prospective randomized, placebo-controlled, double-blind study.

Protection of trial subjects:

No specific protection measures were required due to the specific treatment protocol.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 November 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	Italy: 100
Worldwide total number of subjects	100
EEA total number of subjects	100

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)	100
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Once provided written informed consent, two hundred patients were screened for Hp infection by stool antigen immunochromatography. The first 40 and 60 infected and non-infected patients respectively were enrolled in the protocol for a total of 100 patients.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Group Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Rice starch
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: 3 capsules twice a day for 10 days	
Arm title	Group Active Treatment
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Pantoprazole
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: 40 mg twice a day for 10 days	
Investigational medicinal product name	Clarithromycin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: 500 mg twice a day for 10 days	
Investigational medicinal product name	Amoxicillin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:
1g twice a day for 10 days

Arm title	Non treated patients
Arm description: -	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	Group Placebo	Group Active Treatment	Non treated patients
Started	10	30	60
Completed	9	30	60
Not completed	1	0	0
Lost to follow-up	1	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	100	100	
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)	100	100	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	51	51	
Male	49	49	

End points

End points reporting groups

Reporting group title	Group Placebo
Reporting group description: -	
Reporting group title	Group Active Treatment
Reporting group description: -	
Reporting group title	Non treated patients
Reporting group description: -	

Primary: Improvement of HOMA index

End point title	Improvement of HOMA index
End point description:	
End point type	Primary
End point timeframe:	
6 weeks	

End point values	Group Placebo	Group Active Treatment	Non treated patients	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	30	0[1]	
Units: subjects	5	12		

Notes:

[1] - Endpoint has not been measured because no control visit was performed.

Statistical analyses

Statistical analysis title	Statistical differences in metabolic variables
Comparison groups	Group Placebo v Group Active Treatment
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	t-test, 1-sided

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

6 weeks

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.1

Reporting groups

Reporting group title	Group Placebo
Reporting group description: -	
Reporting group title	Group Active Treatment

Reporting group description: -

Serious adverse events	Group Placebo	Group Active Treatment	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 9 (0.00%)	0 / 30 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0.05 %

Non-serious adverse events	Group Placebo	Group Active Treatment	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 9 (0.00%)	0 / 30 (0.00%)	

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: The short period of treatment has not caused any adverse event.

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