Clinical trial results:
The impact of proton-pump inhibitors (antacids) on threshold dose distributions

Summary

EudraCT number	2015-001863-38
Trial protocol	ES
Global end of trial date	30 June 2018

Results information

Result version number	v1 (current)
This version publication date	12 April 2021
First version publication date	12 April 2021
Summary attachment (see zip file)	Summary (201500186338_SUMMARY.pdf)

Trial information

Trial identification

Sponsor protocol code	iFAAM-PPIwalnut

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Fundación Investigación Biomédica Hospital Clínico San Carlos
Sponsor organisation address	Profesor Martín Lagos s/n, Madrid, Spain, 28040
Public contact	UICEC, Fundación para la investigación biomedica Hospital Clinico San Carlos, +34 9133030007360, fibucicec.hcsc@salud.madrid.org
Scientific contact	UICEC, Fundación para la investigación biomedica Hospital Clinico San Carlos, +34 9133030007360, fibucicec.hcsc@salud.madrid.org

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	25 May 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 June 2018
Global end of trial reached?	Yes
Global end of trial date	30 June 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Investigation of effect of Omeprazole on the threshold dose-distribution curve and the severity of the clinical manifestation of walnut allergic patients

Protection of trial subjects:

No needed to take any special measures aside from performin the trial in a controlled enviroment, according to the actual clinical trials regulation.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 July 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	Spain: 52
Worldwide total number of subjects	52
EEA total number of subjects	52

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)	52
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment started on April 2016 and ended on June 2018

Pre-assignment

Screening details:

- Positive case history of immediate allergic reaction(s) to walnut.
- Age ≥ 18 years.
- Presence of specific IgE to walnut defined as a positive (≥ 3 mm wheal diameter) skin prick test and/or a serum IgE to walnut ≥ 0.35 kU/L (ImmunoCAP).

Period 1

Period 1 title	Overall treatment (crossover design) (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?	No
Arm title	Omeprazole

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Omeprazole Sandoz
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

40mg qd

Arm title	Mannitol

Arm description: -

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

Dosage and administration details:

Mannitol opaque capsule

Number of subjects in period 1	Omeprazole	Mannitol
Started	40	41
Completed	38	38
Not completed	2	3
Consent withdrawn by subject	2	2
Lack of compliance	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Overall treatment (crossover design)

Reporting group description: -

Reporting group values	Overall treatment (crossover design)	Total	
Number of subjects	52	52	
Age categorical			
Adults 18-64			
Units: Subjects			
Adults 18-64	52	52	
Age continuous			
18-64			
Units: years			
median	31.04		
standard deviation	± 10.17	-	
Gender categorical			
Units: Subjects			
Female	32	32	
Male	20	20	

End points

End points reporting groups

Reporting group title	Omeprazole
Reporting group description: -	
Reporting group title	Mannitol
Reporting group description: -	

Primary: Change on the minimal eliciting dose of walnut protein in walnut allergic patients

End point title	Change on the minimal eliciting dose of walnut protein in walnut allergic patients
End point description:	
End point type	Primary
End point timeframe:	
At the moment of food challenge (after 5 days taking the drug)	

End point values	Omeprazole	Mannitol		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	24		
Units: grams	40	41		

Statistical analyses

Statistical analysis title	The effect of omeprazole on walnut threshold
Comparison groups	Omeprazole v Mannitol
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.05
Method	Regression, Cox

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 5th day after taking the drug (druing each food challenge)	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	1
Reporting groups	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Omeprazol
Reporting group description: -	

Serious adverse events	Placebo	Omeprazol	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (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: 2 %

Non-serious adverse events	Placebo	Omeprazol	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 41 (73.17%)	18 / 40 (45.00%)	
Nervous system disorders			
Any nervous system disorder			
subjects affected / exposed	10 / 41 (24.39%)	6 / 40 (15.00%)	
occurrences (all)	30	18	
Gastrointestinal disorders			
Any gastrointestinal disroder			
subjects affected / exposed	10 / 41 (24.39%)	4 / 40 (10.00%)	
occurrences (all)	30	18	
Respiratory, thoracic and mediastinal disorders			
Any respiratory tract disorder			

subjects affected / exposed occurrences (all)	7 / 41 (17.07%) 30	3 / 40 (7.50%) 18	
Skin and subcutaneous tissue disorders Any skin-eye disorder subjects affected / exposed occurrences (all)	 1 / 41 (2.44%) 30	 2 / 40 (5.00%) 18	
Musculoskeletal and connective tissue disorders Any musculo-skeletal subjects affected / exposed occurrences (all)	 2 / 41 (4.88%) 30	 3 / 40 (7.50%) 18	

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