



Clinical trial results:

Phase IV, single centre, randomised, open-label, two-period, two-way crossover clinical trial to assess the efficacy of Bilastine 20mg in the suppression of wheal and flare induced by intradermal histamine in healthy volunteers under fasted and fed conditions.

Summary

EudraCT number	2018-000913-19
Trial protocol	ES
Global end of trial date	03 July 2018

Results information

Result version number	v1 (current)
This version publication date	02 July 2022
First version publication date	02 July 2022

Trial information

Trial identification

Sponsor protocol code	BILA-3818/PD
-----------------------	--------------

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	FAES Farma, S.A.
Sponsor organisation address	Avda Autonomía, 10, Leioa, Spain, 48940
Public contact	Clinical Research Director, FAES FARMA, S.A., 0034 944818300, ccampo@faes.es
Scientific contact	Clinical Research Director, FAES FARMA, S.A., 0034 944818300, ccampo@faes.es

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 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 July 2018
Global end of trial reached?	Yes
Global end of trial date	03 July 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the efficacy of Bilastine 20 mg administered orally under fasted and fed conditions (moderate-fat meal) in reduction of histamine-induced skin reactivity in healthy volunteers, taking into account the first treatment day (Day 1) and steady state (Day 4).

Protection of trial subjects:

Healthy volunteers, study designed to minimize the number of study drug administrations. All study subjects had immediate medical care access if necessary.

Background therapy:

Healthy volunteers, no additional therapies needed

Evidence for comparator:

Not applicable

Actual start date of recruitment	17 May 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	Spain: 24
Worldwide total number of subjects	24
EEA total number of subjects	24

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)	24
From 65 to 84 years	0

85 years and over	0
-------------------	---

Subject disposition

Recruitment

Recruitment details:

A total of 41 subjects were screened for the trial and 29 subjects met the inclusion/exclusion criteria. Twenty-four subjects were randomized and 23 completed their participation on the clinical study.

Pre-assignment

Screening details:

The inclusion phase (four weeks before the beginning of experimental phase) was initiated and all subjects underwent a complete medical check-up in order to verify that they met all the inclusion criteria and none of the exclusion criteria.

Period 1

Period 1 title	Fed condition
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Total population Fed
-----------	----------------------

Arm description:

Total population treated with bilastine once daily under fed conditions

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

Dosage and administration details:

20 mg once daily for 4 days under Fasting conditions

Number of subjects in period 1	Total population Fed
Started	24
Completed	24

Period 2

Period 2 title	Fasting condition
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Total population Fasting
Arm description:	
Total population treated with bilastine once daily under fasting conditions	
Arm type	Experimental
Investigational medicinal product name	Bilastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

20 mg once daily for 4 days under fed conditions

Number of subjects in period 2	Total population Fasting
Started	24
Completed	23
Not completed	1
Patient did not attend the fasting period	1

Baseline characteristics

Reporting groups

Reporting group title	Fed condition
-----------------------	---------------

Reporting group description: -

Reporting group values	Fed condition	Total	
Number of subjects	24	24	
Age categorical			
Units: Subjects			
Adults (18-64 years)	24	24	
Gender categorical			
Units: Subjects			
Female	12	12	
Male	12	12	

Subject analysis sets

Subject analysis set title	Pharmacodynamic profile
----------------------------	-------------------------

Subject analysis set type	Per protocol
---------------------------	--------------

Subject analysis set description:

Subjects who completed the clinical study without protocol deviations.

Reporting group values	Pharmacodynamic profile		
Number of subjects	23		
Age categorical			
Units: Subjects			
Adults (18-64 years)	23		
Gender categorical			
Units: Subjects			
Female	12		
Male	11		

End points

End points reporting groups

Reporting group title	Total population Fed
Reporting group description:	
Total population treated with bilastine once daily under fed conditions	
Reporting group title	Total population Fasting
Reporting group description:	
Total population treated with bilastine once daily under fasting conditions	
Subject analysis set title	Pharmacodynamic profile
Subject analysis set type	Per protocol
Subject analysis set description:	
Subjects who completed the clinical study without protocol deviations.	

Primary: Efficacy of bilastine 20 mg on 1st treatment day (Day 1)

End point title	Efficacy of bilastine 20 mg on 1st treatment day (Day 1)
End point description:	
The primary objective of this study is to compare the efficacy of bilastine 20 mg administered orally under fasting and fed conditions (moderate-fat breakfast) in reduction of histamine-induced skin reactivity in healthy volunteers, taking into account the first treatment day (Day 1)	
End point type	Primary
End point timeframe:	
Day 1	

End point values	Total population Fed	Total population Fasting		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: ngh/mL				
arithmetic mean (standard deviation)	1494.60 (\pm 256.14)	1423.45 (\pm 191.88)		

Statistical analyses

Statistical analysis title	IBM-SPSS 22.0.
Comparison groups	Total population Fed v Total population Fasting
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other ^[1]
P-value	< 0.05
Method	ANOVA

Notes:

[1] - Statistical analyses were performed using the program IBM-SPSS 22.0. In all the statistical analyses the level of significance was set at 5% (alpha value = 0.05), two-sided

Primary: Efficacy of bilastine 20 mg on steady state (Day 4)

End point title	Efficacy of bilastine 20 mg on steady state (Day 4)
End point description: efficacy of bilastine 20 mg administered orally under fasting and fed conditions (moderate-fat breakfast) in reduction of histamine-induced skin reactivity in healthy volunteers, taking into account steady state (Day 4).	
End point type	Primary
End point timeframe: Day 4	

End point values	Total population Fed	Total population Fasting		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: ngh/mL				
arithmetic mean (standard deviation)	1523.48 (± 199.60)	1529.46 (± 242.35)		

Statistical analyses

Statistical analysis title	IBM-SPSS (v22.0)
Comparison groups	Total population Fed v Total population Fasting
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	ANOVA

Secondary: Safety and tolerability

End point title	Safety and tolerability
End point description: To assess the safety and tolerability of bilastine after repeated (4 days) single daily oral dose (20 mg) administration in young male and female healthy volunteers	
End point type	Secondary
End point timeframe: From informed consent signature till final visit	

End point values	Pharmacodynamic profile			
Subject group type	Subject analysis set			
Number of subjects analysed	23			
Units: number	23			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From informed consent signature till final visit

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	21.0
--------------------	------

Reporting groups

Reporting group title	Fasting
-----------------------	---------

Reporting group description: -

Reporting group title	Fed condition
-----------------------	---------------

Reporting group description: -

Serious adverse events	Fasting	Fed condition	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 24 (0.00%)	0 / 24 (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: 5 %

Non-serious adverse events	Fasting	Fed condition	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 24 (8.33%)	3 / 24 (12.50%)	
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 24 (8.33%)	2 / 24 (8.33%)	
occurrences (all)	2	2	
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 24 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	

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