Clinical trial results:
Double-blind, triple cross-over, placebo-controlled study to assess the efficacy, mechanisms, and safety of treatment with bilastine 20 mg, 40 mg and 80 mg in cold contact urticaria (CCU)
Compound: Bilastine

Summary

EudraCT number	2010-019344-39
Trial protocol	DE
Global end of trial date	26 August 2011
Results information	
Result version number	v1 (current)
This version publication date	27 November 2021
First version publication date	27 November 2021
Summary attachment (see zip file)	Final Report (BUCUM_Final report_27.8.12-komprimiert.pdf)

Trial information

Trial identification	
Sponsor protocol code	BUCUM1
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors	
Sponsor organisation name	Allergie-Centrum-Charité
Sponsor organisation address	Charitéplatz 1, Berlin, Germany, 10117
Public contact	Prof. Dr. M. Maurer, Department of Dermatology and Allergy Charité - Universitätsmedizin Berlin, marcus.maurer@charite.de
Scientific contact	Prof. Dr. M. Maurer, Department of Dermatology and Allergy Charité - Universitätsmedizin Berlin, marcus.maurer@charite.de
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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	26 August 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 August 2011
Global end of trial reached?	Yes
Global end of trial date	26 August 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the effects of a standard dose (20 mg) and higher than standard doses of bilastine (40 mg and 80 mg) on symptom development during the induction of skin lesions in cold contact urticaria (CCU) patients challenged with defined temperatures using TEMPtest 3.0.

Protection of trial subjects:

Bilastine encoded F-96221-BM1, 2-[4-(2-(4-(1-(2-ethoxyethyl)-1H-benzimidazol-2-yl)piperidin-1-yl)ethyl)phenyl]-2-methylpropionic acid, is a novel drug substance which has been developed by FAES FARMA for the treatment of the symptoms of allergic rhinoconjunctivitis and urticaria. It is a new H1 antagonist with no sedative side effects and no cardiotoxic effects. The target dose of bilastine is a tablet of 20 mg once daily. In a randomized double-blind placebo-controlled study with 525 patients it has been shown that bilastine 20 mg is effective and safe in reducing clinical symptoms in chronic spontaneous urticaria (12).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 September 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	16
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

All patients
included in this study will be subjected at the screening visit (V1) to a physical examination.
If the diagnosis of CCU has not been confirmed in the past, an additional
cold provocation test with 4°C will be performed us ing Temptest 3.0. At V2, patients will
be tested for CCU symptom development.

Period 1

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

Arms

Arm title	Baseline
Arm description: -	
Arm type	Baseline
Investigational medicinal product name	Bilastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablets containing 20 mg bilastine.

Number of subjects in period 1	Baseline
Started	20
Completed	20

Period 2

Period 2 title	Treatment 1-4
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Arm title	Treatment 1-4

Arm description:

Patients will then be given 1) bilastine 40 mg daily or 2) placebo for 7 days according to the randomisation at V2. All patients will be told to start with the medication 1) or 2) after completion of a two-week washout-period. At the end of the 7-day treatment phase patients will return for V4 and again be tested for CCU symptom development. After another two-week washout-period patients will receive either 1) bilastine 40 mg daily or 2) placebo for 7 days (according to the randomization at V2). At the end of the 7-day treatment phase patients will return for V5 and again be tested for CCU symptom development. After yet another two-week washout-period patients will receive either 1) bilastine 80 mg daily or 2) bilastine 20 mg for 7 days (according to the randomization at V2). At the end of the 7-day treatment phase patients will return for V6 and again be tested for CCU symptom development.

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

Dosage and administration details:

Sequence A: 20 mg 40 mg Placebo 80 mg
Sequence B: 80 mg Placebo 40 mg 20 mg

See Final report

Number of subjects in period 2	Treatment 1-4
Started	20
Completed	20

Baseline characteristics

End points

End points reporting groups

Reporting group title	Baseline
Reporting group description: -	
Reporting group title	Treatment 1-4

Reporting group description:

Patients will then be given 1) bilastine 40 mg daily or 2) placebo for 7 days according to the randomisation at V2. All patients will be told to start with the medication 1) or 2) after completion of a two-week washout-period. At the end of the 7-day treatment phase patients will return for V4 and again be tested for CCU symptom development. After another two-week washout-period patients will receive either 1) bilastine 40 mg daily or 2) placebo for 7 days (according to the randomization at V2). At the end of the 7-day treatment phase patients will return for V5 and again be tested for CCU symptom development. After yet another two-week washout-period patients will receive either 1) bilastine 80 mg daily or 2) bilastine 20 mg for 7 days (according to the randomization at V2). At the end of the 7-day treatment phase patients will return for V6 and again be tested for CCU symptom development.

Primary: Primary endpoint

End point title	Primary endpoint[1]

End point description:

Sequence A: 20 mg, 40 mg, Placebo, 80 mg
Sequence B: 80 mg, Placebo, 40 mg, 20 mg
The endpoint value refers to bilastine 20mg as an example. For the other groups please see final report.

End point type	Primary

End point timeframe:

12 weeks

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: See final report

End point values	Treatment 1-4			
Subject group type	Reporting group			
Number of subjects analysed	20[2]			
Units: critical stimulation time thresholds (CS				
median (inter-quartile range (Q1-Q3))	270 (157.5 to 300)			

Notes:

[2] - For example: Treatment group 20mg

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

During the whole trial.

See final report

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20

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: See final report

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