Clinical trial results:
Disease activity controlled dose escalating study to assess the efficacy, and safety of treatment with bilastine 20 mg, 40 mg and 80 mg in chronic spontaneous urticaria.

Summary

EudraCT number	2014-000181-21
Trial protocol	DE
Global end of trial date	05 March 2016

Results information

Result version number	v1 (current)
This version publication date	13 February 2022
First version publication date	13 February 2022
Summary attachment (see zip file)	Final Report (Final_Report_BUCSU_22FEB2017.pdf)

Trial information

Trial identification

Sponsor protocol code	BUCSU

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Charite - Universitätsmedizin Berlin
Sponsor organisation address	Charitéplatz 1 , Berlin, Germany, 10117
Public contact	Allergie-Centrum-Charite, Charite - Universitätsmedizin Berlin, +49 030450518042, marcus.maurer@charite.de
Scientific contact	Allergie-Centrum-Charite, Charite - Universitätsmedizin Berlin, +49 030450518042, marcus.maurer@charite.de

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	05 March 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 March 2016
Global end of trial reached?	Yes
Global end of trial date	05 March 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the effects of standard dose (20 mg) and higher than standard dose of bilastine (40 mg and 80 mg) on disease activity in patients with chronic spontaneous urticaria.

Protection of trial subjects:

A total number of 30 patients with moderate to severe chronic spontaneous urticaria, all of which had previously failed treatment with an antihistamine other than bilastine in standard (licensed) dose, were planned to be included into the study. Until the end of the trial, 31 patients were randomized and analyzed.
The evaluation of efficacy and safety was carried out on the intention-to-treat population.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 May 2015
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: 31
Worldwide total number of subjects	31
EEA total number of subjects	31

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)	21
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

During the first two weeks (14 2 days) of the study (screening phase) all patients were administered with one tablet bilastine 20 mg daily p.o. as rescue medication. This tablet should only be taken in case of intolerable CSU symptoms and the intake had to be documented in the patient diary.

Period 1

Period 1 title	Treatment (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Bilastine 20/40/80 mg

Arm description:

During the first two weeks of the following treatment phase all patients were asked to take one tablet bilastine 20 mg p.o. once daily. In case the patients did not achieve complete response, they changed to 40 mg bilastine p.o. (2 tablets containing bilastine 20 mg once daily) for the next two weeks, while those with complete response stayed on 20 mg bilastine p.o. once daily for the rest of the study. After another two weeks, response to treatment was again reviewed. Those patients who did not achieve complete response to 40 mg bilastine p.o. were further updosed to 80 mg bilastine p.o. (4 tablets containing bilastine 20 mg once daily), while those with complete response stayed on the 40 mg dose p.o. for the rest of the trial. The total duration of the treatment phase was 6 weeks.

Arm type	Active comparator
Investigational medicinal product name	Bilastine
Investigational medicinal product code	ATC-Code: R06AX29)
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

20, 40 and 80 mg bilastine

Number of subjects in period 1	Bilastine 20/40/80 mg
Started	31
Completed	31

Baseline characteristics

End points

End points reporting groups

Reporting group title	Bilastine 20/40/80 mg

Reporting group description:

During the first two weeks of the following treatment phase all patients were asked to take one tablet bilastine 20 mg p.o. once daily. In case the patients did not achieve complete response, they changed to 40 mg bilastine p.o. (2 tablets containing bilastine 20 mg once daily) for the next two weeks, while those with complete response stayed on 20 mg bilastine p.o. once daily for the rest of the study. After another two weeks, response to treatment was again reviewed. Those patients who did not achieve complete response to 40 mg bilastine p.o. were further updosed to 80 mg bilastine p.o. (4 tablets containing bilastine 20 mg once daily), while those with complete response stayed on the 40 mg dose p.o. for the rest of the trial. The total duration of the treatment phase was 6 weeks.

Primary: Comparison of the rate of complete responders (reduction of the UAS7 by at least 90% (as compared to baseline) or a UAS7 ≤ 3) between the second (20 mg bilastine), fourth (20 mg or 40 mg bilastine) and sixth week (20 mg, 40 mg or 80 mg bilastine) of the t

End point title	Comparison of the rate of complete responders (reduction of the UAS7 by at least 90% (as compared to baseline) or a UAS7 ≤ 3) between the second (20 mg bilastine), fourth (20 mg or 40 mg bilastine) and sixth week (20 mg, 40 mg or 80 mg bilastine) of the t[1]

End point description:

End point type	Primary

End point timeframe:

The total duration of the treatment phase was 6 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	Bilastine 20/40/80 mg			
Subject group type	Reporting group			
Number of subjects analysed	31			
Units: UAS7				
number (not applicable)	31			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: During the whole study.	
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