Clinical trial results:
A Multicenter, Randomized, Double-Blind, Monotherapy-Controlled Study of Nifedipine Gastrointestinal Therapeutic System and Candesartan Cilexetil in Combination Taken Orally for 8 Weeks in Adult Subjects with Essential Hypertension Who Are Inadequately Controlled on 16 mg Candesartan Cilexetil Monotherapy

Summary

EudraCT number	2012-004493-26
Trial protocol	DE BE CZ GB ES PL LT FR
Global end of trial date	28 September 2016

Results information

Result version number	v1 (current)
This version publication date	03 December 2019
First version publication date	03 December 2019
Summary attachment (see zip file)	Withdrawn statement (Withdrawn Statement.pdf)

Trial information

Trial identification

Sponsor protocol code	BAY98-7106/14727

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02047019
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bayer AG
Sponsor organisation address	Kaiser Wilhelm Allee, Leverkusen, Germany, D-51368
Public contact	Therapeutic Area Head, Bayer AG, clinical-trials-contact@bayer.com
Scientific contact	Therapeutic Area Head, Bayer AG, clinical-trials-contact@bayer.com

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	28 September 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 September 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to demonstrate the efficacy of two FDCs of nifedipine GITS and candesartan cilexetil compared to candesartan cilexetil monotherapy in subjects not adequately controlled on candesartan cilexetil alone, based on reduction of mean seated systolic blood pressure (MSSBP).

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 September 2016
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	Germany: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial.

Pre-assignment

Screening details:

N/A

Period 1

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

Arms

Arm title	Overall Trial

Arm description:

99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial.

Arm type	Experimental
Investigational medicinal product name	Nifedipine GITS/Candesartan cilexetil 30/16
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

NifedipineGITS/candesartan cilexetil 30/16 mg
Orally, once daily in the morning

Investigational medicinal product name	Nifedipine GITS/Candesartan cilexetil 60/16
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

NifedipineGITS/candesartan cilexetil 60/16 mg
Orally, once daily in the morning

Number of subjects in period 1	Overall Trial
Started	99999
Completed	99999

Baseline characteristics

Reporting groups	
Reporting group title	Overall Trial
Reporting group description:	
99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial.	

Reporting group values	Overall Trial	Total	
Number of subjects	99999	99999	
Age categorical			
Units: Subjects			

Age continuous			
99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial.			
Units: years			
arithmetic mean	0		
standard deviation	± 0	-	
Gender categorical			
99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial.			
Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Overall Trial

Reporting group description:

99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial.

Primary: Change from baseline in mean seated systolic blood pressure (MSSBP) at Week 8

End point title	Change from baseline in mean seated systolic blood pressure (MSSBP) at Week 8[1]

End point description:

99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial.

End point type	Primary

End point timeframe:

N/A

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: No subjects were enrolled in the trial. Consequently, no results are available for this trial.

End point values	Overall Trial			
Subject group type	Reporting group			
Number of subjects analysed	99999[2]			
Units: 99999	99999			

Notes:

[2] - No subjects were enrolled in the trial hence results are not available

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

N/A

Adverse event reporting additional description:

99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0

Reporting groups

Reporting group title	Overall Trial

Reporting group description:

99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial.

Serious adverse events	Overall Trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Overall Trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 99999 (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: No subjects were enrolled in the trial. Consequently, no results are available for this trial.

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial. Consequently, no results are available for this trial.

Notes: