



## 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 Nifedipine Gastrointestinal Therapeutic System Monotherapy**

#### **Summary**

EudraCT number	2012-004857-10
Trial protocol	DE IT
Global end of trial date	28 September 2016

#### **Results information**

Result version number	v1 (current)
This version publication date	03 May 2020
First version publication date	03 May 2020
Summary attachment (see zip file)	Withdrawn Statement (Withdrawn Statement.pdf)

#### **Trial information**

##### **Trial identification**

Sponsor protocol code	BAY98-7106/14728
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##### **Additional study identifiers**

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
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:

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**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:

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**General information about the trial**

Main objective of the trial:

The primary objective is to demonstrate the superior efficacy of the FDC of nifedipine GITS and candesartan cilexetil compared to nifedipine GITS monotherapy in subjects with essential hypertension not adequately controlled on nifedipine GITS alone, based on reduction of 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:

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**Population of trial subjects**

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**Subjects enrolled per country**

Country: Number of subjects enrolled	Germany: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

Notes:

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**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)	0
From 65 to 84 years	99999
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
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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 30/8 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

NifedipineGITS/candesartan cilexetil 30/8 mg Orally, once daily in the morning

Investigational medicinal product name	Nifedipine GITS/Candesartan Cilexetil 30/16 mg
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 30 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Prolonged-release tablet
Routes of administration	Oral use

Dosage and administration details:

Nifedipine GITS 30 mg Orally, once daily in the morning

<b>Number of subjects in period 1</b>	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			
99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial.			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	99999	99999	
85 years and over	0	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 8change from baseline in MSSBP at Week 8

End point title	Change from baseline in mean seated systolic blood pressure (MSSBP) at Week 8change from baseline in MSSBP at Week 8 <sup>[1]</sup>
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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
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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 <sup>[2]</sup>			
Units: Number of subjects analysed	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<sup>[1]</sup>

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
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	0
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### Reporting groups

Reporting group title	Overall Trial
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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: 0 %

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

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### 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.
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Notes: