



Clinical trial results:

Patient pREference and satisFaction for pErindopril oRodispersible vs convENTional tablets in daily Clinical practicE.

PREFERENCE

Summary

EudraCT number	2011-003328-11
Trial protocol	FR
Global end of trial date	28 April 2014

Results information

Result version number	v1
This version publication date	26 November 2016
First version publication date	26 November 2016

Trial information

Trial identification

Sponsor protocol code	DM4-90652-001
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Institut de Recherches Internationales Servier
Sponsor organisation address	50 rue Carnot, Suresnes, France,
Public contact	Clinical Studies Department, Institut de Recherches Internationales Servier, 33 01 55 72 43 66, clinicaltrials@servier.com
Scientific contact	Clinical Studies Department, Institut de Recherches Internationales Servier, 33 01 55 72 43 66, clinicaltrials@servier.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 April 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 April 2014
Global end of trial reached?	Yes
Global end of trial date	28 April 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To study, in hypertensive patients, followed in general practice and whose Blood Pressure is well controlled by a monotherapy with tablets of perindopril arginine, their preference and acceptability in favour of the orodispersible form of this medicinal product 1 month after changing the dosage form.

Protection of trial subjects:

This study was conducted in accordance with Good Clinical Practice standards, ethical principles stated in the Declaration of Helsinki and applicable regulatory requirements. After the subject has ended his/her participation in the trial, the investigator provided appropriate medication and/or arranged access to appropriate care for the patient.

Background therapy:

Before entry in the study patients were treated by their doctor with perindopril arginine 5 or 10 mg per day administered as tablet, and at the same dose for at least 3 months

Evidence for comparator: -

Actual start date of recruitment	22 February 2013
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	3 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 12
Worldwide total number of subjects	12
EEA total number of subjects	12

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)	8
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

- Adult male or female, without upper limit for the age, with arterial hypertension (systolic blood pressure > 140 mm Hg or diastolic blood pressure > 90 mmHg) previously treated with perindopril arginine as tablet, 5 or 10 mg per day, and at stable dose for at least 3 months

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	12
Number of subjects completed	12

Period 1

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

Arms

Arm title	Perindopril arginine orodispersible
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Arm description:

an orodispersible tablet of perindopril arginine at posology of 5 or 10 mg per day over a maximum period of 3 months.

Arm type	Experimental
Investigational medicinal product name	Perindopril arginine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Orodispersible tablet
Routes of administration	Oral use

Dosage and administration details:

5 or 10 mg/day

Number of subjects in period 1	Perindopril arginine orodispersible
Started	12
Completed	12

Baseline characteristics

Reporting groups

Reporting group title	Perindopril arginine orodispersible
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Reporting group description:

an orodispersible tablet of perindopril arginine at posology of 5 or 10 mg per day over a maximum period of 3 months.

Reporting group values	Perindopril arginine orodispersible	Total	
Number of subjects	12	12	
Age categorical			
Of note for one patient the age was missing. However, this patient had an ongoing professional activity and was a senior officer. Therefore, the age of this patient was probably between 18 and 64 years, and was filled in the 18-64 years age category hereafter.			
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)	8	8	
From 65-84 years	4	4	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	6	6	
Male	6	6	

End points

End points reporting groups

Reporting group title	Perindopril arginine orodispersible
Reporting group description: an orodispersible tablet of perindopril arginine at posology of 5 or 10 mg per day over a maximum period of 3 months.	

Primary: Preference for orodispersible versus tablet perindopril arginine form at one month

End point title	Preference for orodispersible versus tablet perindopril arginine form at one month ^[1]
End point description: 5 questions were included in the questionnaire that was filled in after one month after patient's inclusion - Question 1 : Preference for orodispersible form (versus tablet) ? - Question 2: Is orodispersible form the most convenient ? - Question 3 : Is orodispersible form the most appropriate ? - Question 4: Would you use orodispersible form for a long treatment period ? - Question 5 : Would you use orodispersible form for the further 2 months ? As no statistical analysis of the questionnaire was conducted due to the low number of patients included in the study, the endpoint described hereafter correspond to the answer to the question 1. Of note the same score was obtained for question 2, 3, 4, and at question 5 all patients responded that they would use for further 2 months the orodispersible perindopril arginine form.	
End point type	Primary
End point timeframe: Over 30 days	

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: A low number of patients could be included in the study (n = 12) compared to the number planned (n = 100), due to difficulty to recruit patients that led to premature study discontinuation. Therefore it had been decided to not carry out statistical analysis of the questionnaires.

End point values	Perindopril arginine orodispersible			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: number of patients	5			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Overall study

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	14.1
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Reporting groups

Reporting group title	Perindopril arginine orodispersible
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Reporting group description: -

Serious adverse events	Perindopril arginine orodispersible		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (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	Perindopril arginine orodispersible		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 12 (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: This study was conducted in very few patients, followed by their doctor, for whom the arterial hypertension was well controlled with perindopril arginine 5 or 10 mg per day administered as tablet for at least 3 months. In the Preference study patients switched from this background therapy to the same product same dose but with an orodispersible form, on a short duration. None of the patients reported as medical history co-morbidities. It is probably why no non-serious adverse event occurred.

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? Yes

Date	Interruption	Restart date
28 April 2014	It was decided to stop the study due to difficulty to recruit patients. Therefore only 12 patients out of 100 planned were included (with a duration of almost one year between the first and last included patient) and completed the study.	-

Notes:

Limitations and caveats

None reported