



Clinical trial results:

Safety and intake effect of EPs®7630 (an extract from the roots of Pelargonium sidoides)

Summary

EudraCT number	2013-004977-28
Trial protocol	GB
Global end of trial date	31 August 2016

Results information

Result version number	v1 (current)
This version publication date	01 July 2018
First version publication date	01 July 2018
Summary attachment (see zip file)	701079.01.013 Summary of results 2016_09_07 (701079.01.013 Summary of Results_EudraCT_Version 1.0_mit Schwärzungen_20170907.pdf)

Trial information

Trial identification

Sponsor protocol code	701079.01.013
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Additional study identifiers

ISRCTN number	ISRCTN35425744
ClinicalTrials.gov id (NCT number)	NCT02174653
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Dr. Willmar Schwabe GmbH & Co. KG
Sponsor organisation address	Willmar Schwabe Str. 4, Karlsruhe, Germany, 76227
Public contact	Head Clinical Research, Dr. Willmar Schwabe GmbH & Co. KG, 0049 7214005573,
Scientific contact	Head Clinical Research, Dr. Willmar Schwabe GmbH & Co. KG, 0049 7214005573,

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	29 January 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 July 2015
Global end of trial reached?	Yes
Global end of trial date	31 August 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to investigate the occurrence of adverse drug reactions (ADRs) during the 4 months treatment, defined as the proportion of participants in each trial group with suspected adverse events.

Protection of trial subjects:

Possibility to withdraw consent. Monitoring of adverse Events and laboratory Parameters.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 March 2014
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	United Kingdom: 798
Worldwide total number of subjects	798
EEA total number of subjects	798

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)	797
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

n.a.

Pre-assignment

Screening details:

Seventy eight participants were not randomized and did not receive the investigational product since they did not fulfill all in-/exclusion criteria.

Pre-assignment period milestones

Number of subjects started	798
Number of subjects completed	683

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Screening Failures: 78
Reason: Number of subjects	No Intake of Study Medication: 37

Period 1

Period 1 title	Treatment period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	EPs® 7630

Arm description:

EPs® 7630 3x20 mg or 3x20/40 mg film-coated tablets

Arm type	Experimental
Investigational medicinal product name	EPs® 7630
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

3x20 mg / 3x40 mg

Arm title	Placebo
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Arm description:

Placebo film-coated tablets

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

Dosage and administration details:

3x0 mg

Number of subjects in period 1^[1]	EPs® 7630	Placebo
Started	460	223
Completed	425	213
Not completed	35	10
Adverse event, non-fatal	2	-
Other	10	3
Withdrawal of consent without giving the reason	5	-
Lost to follow-up	18	7

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: 78 Screening Failures and 37 subjects with no intake of study medication.

Baseline characteristics

Reporting groups

Reporting group title	EPs® 7630
Reporting group description: EPs® 7630 3x20 mg or 3x20/40 mg film-coated tablets	
Reporting group title	Placebo
Reporting group description: Placebo film-coated tablets	

Reporting group values	EPs® 7630	Placebo	Total
Number of subjects	460	223	683
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	459	223	682
From 65-84 years	1	0	1
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	21.7	21	
standard deviation	± 6.6	± 5	-
Gender categorical Units: Subjects			
Female	291	148	439
Male	169	75	244

Subject analysis sets

Subject analysis set title	Safety analysis set
Subject analysis set type	Safety analysis
Subject analysis set description: Safety Analysis set	

Reporting group values	Safety analysis set		
Number of subjects	683		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	682		
From 65-84 years	1		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean	21.5		
standard deviation	± 6.1		
Gender categorical			
Units: Subjects			
Female	439		
Male	244		

End points

End points reporting groups

Reporting group title	EPs® 7630
Reporting group description:	EPs® 7630 3x20 mg or 3x20/40 mg film-coated tablets
Reporting group title	Placebo
Reporting group description:	Placebo film-coated tablets
Subject analysis set title	Safety analysis set
Subject analysis set type	Safety analysis
Subject analysis set description:	Safety Analysis set

Primary: Occurrence of adverse drug reactions (ADRs) during the 4 months treatment, defined as the proportion of participants in each trial group with suspected adverse events

End point title	Occurrence of adverse drug reactions (ADRs) during the 4 months treatment, defined as the proportion of participants in each trial group with suspected adverse events
End point description:	Note: Occurrence of adverse drug reactions is the primary pre-specified endpoint. See document for a complete description of the endpoints.
End point type	Primary
End point timeframe:	Baseline and End of Treatment (4 month Treatment Period)

End point values	EPs® 7630	Placebo	Safety analysis set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	460	223	683	
Units: Number of ADR				
number (not applicable)	89	43	132	

Statistical analyses

Statistical analysis title	Occurrence of adverse drug reactions
Comparison groups	EPs® 7630 v Placebo
Number of subjects included in analysis	683
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Risk difference (RD) %
Point estimate	0.07

Confidence interval	
level	Other: 97.5 %
sides	1-sided
upper limit	6.4

Adverse events

Adverse events information

Timeframe for reporting adverse events:

4 Months

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	18
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

Placebo

Reporting group title	EPs®7630
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Reporting group description:

EPs®7630

Serious adverse events	Placebo	EPs®7630	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 223 (0.00%)	3 / 460 (0.65%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 223 (0.00%)	1 / 460 (0.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 223 (0.00%)	1 / 460 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious mononucleosis			
subjects affected / exposed	0 / 223 (0.00%)	1 / 460 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Non-serious adverse events	Placebo	EPs®7630	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	65 / 223 (29.15%)	135 / 460 (29.35%)	
Nervous system disorders			
Headache			
subjects affected / exposed	40 / 223 (17.94%)	82 / 460 (17.83%)	
occurrences (all)	95	198	
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	14 / 223 (6.28%)	36 / 460 (7.83%)	
occurrences (all)	27	53	
Nausea			
subjects affected / exposed	13 / 223 (5.83%)	18 / 460 (3.91%)	
occurrences (all)	15	28	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	13 / 223 (5.83%)	20 / 460 (4.35%)	
occurrences (all)	20	30	
Oropharyngeal pain			
subjects affected / exposed	31 / 223 (13.90%)	33 / 460 (7.17%)	
occurrences (all)	48	49	

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