



Clinical trial results:

A Phase 2 Open-Label, Multicenter, 4-Week Study to Assess the safety and Effectiveness of Daily Oral Administration of Dexlansoprazole Delayed-Release Capsules for Relief of Heartburn, in Adolescent subjects Aged 12 to 17 Years With Symptomatic Non-Erosive Gastroesophageal Reflux Disease

Summary

EudraCT number	2012-001680-72
Trial protocol	HU PT BE IT
Global end of trial date	21 January 2014

Results information

Result version number	v1 (current)
This version publication date	04 March 2016
First version publication date	15 July 2015

Trial information

Trial identification

Sponsor protocol code	TAK-390MR_206
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01642602
WHO universal trial number (UTN)	U1111-1128-5977

Notes:

Sponsors

Sponsor organisation name	Takeda Development Centre Europe Ltd.
Sponsor organisation address	61 Aldwych, London, United Kingdom, WC2B 4AE
Public contact	Program Manager, Takeda Development Centre Europe Ltd., 0044 20 3116 8000, clinicaloperations@tgrd.com
Scientific contact	Program Manager, Takeda Development Centre Europe Ltd., 0044 20 3116 8000, clinicaloperations@tgrd.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	21 January 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 January 2014
Global end of trial reached?	Yes
Global end of trial date	21 January 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to assess the safety and effectiveness of treatment with once daily oral administration of dextansoprazole delayed-release capsules in adolescent participants with symptomatic non-erosive gastroesophageal reflux Disease (GERD).

Protection of trial subjects:

All study participants were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 June 2012
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	Poland: 7
Country: Number of subjects enrolled	Portugal: 6
Country: Number of subjects enrolled	Belgium: 1
Country: Number of subjects enrolled	Hungary: 11
Country: Number of subjects enrolled	Italy: 1
Country: Number of subjects enrolled	United States: 66
Country: Number of subjects enrolled	Mexico: 10
Country: Number of subjects enrolled	Brazil: 2
Worldwide total number of subjects	104
EEA total number of subjects	26

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)	104
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at 36 sites in the United States, Belgium, Hungary, Italy, Poland, Portugal, Brazil, and Mexico from 22 June 2012 to 21 January 2014.

Pre-assignment

Screening details:

Adolescent subjects (male or female), aged 12 to 17 years (inclusive) with symptomatic non-erosive gastrointestinal reflux disease were enrolled in 1 group and received dexlansoprazole 30 mg orally once a day for 4 weeks.

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	Dexlansoprazole 30 mg
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Arm description:

Dexlansoprazole 30 mg delayed-release capsules orally once daily for up to 4 weeks.

Arm type	Experimental
Investigational medicinal product name	Dexlansoprazole
Investigational medicinal product code	
Other name	Dexilant
Pharmaceutical forms	Prolonged-release capsule, soft
Routes of administration	Oral use

Dosage and administration details:

Dexlansoprazole delayed-release capsules.

Number of subjects in period 1	Dexlansoprazole 30 mg
Started	104
Completed	102
Not completed	2
Adverse event, non-fatal	2

Baseline characteristics

Reporting groups

Reporting group title	Dexlansoprazole 30 mg
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Reporting group description:

Dexlansoprazole 30 mg delayed-release capsules orally once daily for up to 4 weeks.

Reporting group values	Dexlansoprazole 30 mg	Total	
Number of subjects	104	104	
Age categorical			
Units: Subjects			
12-14 years	34	34	
15-17 years	70	70	
Age continuous			
Units: years			
arithmetic mean	15		
standard deviation	± 1.5	-	
Gender categorical			
Units: Subjects			
Female	73	73	
Male	31	31	
Race/Ethnicity			
Units: Subjects			
Black or African American	0	0	
White	0	0	
Multiracial	0	0	
Hispanic or Latino	19	19	
Non-Hispanic and Latino	47	47	
Not Collected	38	38	
Smoking Classification			
Units: Subjects			
Never Smoked	103	103	
Ex-smoker	1	1	
H pylori Status			
Units: Subjects			
Positive	14	14	
Negative	90	90	
Weight			
Units: kg			
arithmetic mean	61.6		
standard deviation	± 14.393	-	
Height			
Units: cm			
arithmetic mean	163.1		
standard deviation	± 7.58	-	
Body mass index (BMI)			
Units: kg/m ²			
arithmetic mean	23.02		

standard deviation	± 4.434	-	
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End points

End points reporting groups

Reporting group title	Dexlansoprazole 30 mg
Reporting group description: Dexlansoprazole 30 mg delayed-release capsules orally once daily for up to 4 weeks.	
Subject analysis set title	Full analysis set
Subject analysis set type	Full analysis
Subject analysis set description: All participants who received at least 1 dose of study drug and had post-baseline data (and baseline data if applicable) for the efficacy variable.	

Primary: Percent of Participants who Experience Each Treatment Emergent Adverse Event experienced by $\geq 5\%$ of participants while receiving dexlansoprazole during the 4 week Treatment Period

End point title	Percent of Participants who Experience Each Treatment Emergent Adverse Event experienced by $\geq 5\%$ of participants while receiving dexlansoprazole during the 4 week Treatment Period ^[1]
End point description: A Treatment Emergent Adverse Event (TEAE) is defined as an Adverse Event (AE) that started or worsened on or after Study Day 1 (defined as first dose day), and no more than 30 days after the last dose of study drug.	
End point type	Primary
End point timeframe: 4 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: No statistical analysis was performed as there is only 1 reporting group.

End point values	Dexlansoprazole 30 mg			
Subject group type	Reporting group			
Number of subjects analysed	104			
Units: Participants				
number (not applicable)				
Diarrhoea	6.7			
Headache	6.7			

Statistical analyses

No statistical analyses for this end point

Secondary: The percentage of days with neither daytime nor nighttime heartburn over the 4 weeks of treatment

End point title	The percentage of days with neither daytime nor nighttime heartburn over the 4 weeks of treatment
End point description: Participants documented the presence or absence and the degree to which daytime and nighttime heartburn symptoms hurt daily in an electronic daily diary.	

End point type	Secondary
End point timeframe:	
4 weeks	

End point values	Dexlansoprazole 30 mg			
Subject group type	Reporting group			
Number of subjects analysed	104			
Units: Days				
median (full range (min-max))	47.3 (0 to 100)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

A Treatment Emergent Adverse Event (TEAE) is defined as an Adverse Event (AE) that started or worsened on or after Study Day 1 (defined as first dose day), and no more than 30 days after the last dose of study drug.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	16.1

Reporting groups

Reporting group title	Dexlansoprazole 30 mg
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Reporting group description:

Dexlansoprazole 30 mg delayed-release capsules orally once daily for up to 4 weeks.

Serious adverse events	Dexlansoprazole 30 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 104 (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	Dexlansoprazole 30 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 104 (13.46%)		
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 104 (6.73%)		
occurrences (all)	8		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	7 / 104 (6.73%)		
occurrences (all)	7		

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