Clinical trial results:
Cardiac effects of inhibition of the renin angiotensin system with losartan in patients with hypertrophic cardiomyopathy.

Summary

EudraCT number	2011-001191-19
Trial protocol	DK
Global end of trial date	15 April 2014

Results information

Result version number	v1 (current)
This version publication date	02 July 2021
First version publication date	02 July 2021

Trial information

Trial identification

Sponsor protocol code	2011-400

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01447654
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Rigshospitalet
Sponsor organisation address	Blegdamsvej 9, København Ø, Denmark, 2100
Public contact	Henning Bundgaard, Hjertemedicinsk klinik B, 2142, Rigshospitalet, +45 35450512, henningbundgaard@dadlnet.dk
Scientific contact	Henning Bundgaard, Hjertemedicinsk klinik B, 2142, Rigshospitalet, +45 35450512, henningbundgaard@dadlnet.dk

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 June 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 April 2014
Global end of trial reached?	Yes
Global end of trial date	15 April 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess whether treatment with losartan reduces left ventricular mass in patients with hypertrophic cardiomyopathy.

Protection of trial subjects:

None.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 November 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 133
Worldwide total number of subjects	133
EEA total number of subjects	133

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)	110
From 65 to 84 years	23
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment period: Dec 1, 2011, and May 1, 2013.

Pre-assignment

Screening details:

318 patients were screened.

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	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description: -

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:

100 mg per day

Arm title	Losartan

Arm description: -

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

Dosage and administration details:

100 mg per day

Number of subjects in period 1	Placebo	Losartan
Started	69	64
Completed	69	64

Baseline characteristics

Reporting groups

Reporting group title	Treatment period

Reporting group description: -

Reporting group values	Treatment period	Total	
Number of subjects	133	133	
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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
arithmetic mean	52		
standard deviation	± 13	-	
Gender categorical Units: Subjects			
Female	47	47	
Male	86	86	

End points

End points reporting groups	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Losartan
Reporting group description: -	

Primary: Left ventricular mass	
End point title	Left ventricular mass
End point description:	
End point type	Primary
End point timeframe: 12 months	

End point values	Placebo	Losartan		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66	58		
Units: g/m2				
arithmetic mean (standard deviation)	-4 (± 12)	-6 (± 13)		

Statistical analyses

Statistical analysis title	Primary endpoint
Comparison groups	Placebo v Losartan
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Confidence interval	
level	95 %
sides	2-sided

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 12 months	
Assessment type	Systematic
Dictionary used	
Dictionary name	SUSAR
Dictionary version	1
Reporting groups	
Reporting group title	Adverse event

Reporting group description: -

Serious adverse events	Adverse event		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 133 (1.50%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	0		
General disorders and administration site conditions			
Death			
subjects affected / exposed	2 / 133 (1.50%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Adverse event		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 133 (2.26%)		
Skin and subcutaneous tissue disorders			
Angiooedema			
subjects affected / exposed	1 / 133 (0.75%)		
occurrences (all)	1		
Renal and urinary disorders			
Renal impairment			
subjects affected / exposed	1 / 133 (0.75%)		
occurrences (all)	1		
Psychiatric disorders			

Hyperkalemia subjects affected / exposed occurrences (all)	1 / 133 (0.75%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 January 2012	Change in randomization process. Change in acceptables leves of Creatinin and lever enzymes

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported