



Clinical trial results:

A randomized, double-blind, placebo-controlled clinical trial assessing the efficacy of combining pasireotide with aspiration sclerotherapy to improve volume reduction of dominant hepatic cysts

Summary

EudraCT number	2013-003168-29
Trial protocol	NL
Global end of trial date	01 April 2016

Results information

Result version number	v1 (current)
This version publication date	11 October 2022
First version publication date	11 October 2022
Summary attachment (see zip file)	Publication study 2013-003168-29 (Publication study 2013-003168-29.pdf)

Trial information

Trial identification

Sponsor protocol code	JDTW45115
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02048319
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Radboud University Medical Center
Sponsor organisation address	Geert Grooteplein zuid 10, Nijmegen, Netherlands,
Public contact	Wijnands, TFM, Radboud University Nijmegen Medical Center, 0031 243614760, t.wijnands@mdl.umcn.nl
Scientific contact	Wijnands, TFM, Radboud University Nijmegen Medical Center, 0031 243614760, t.wijnands@mdl.umcn.nl

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	01 April 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 April 2016
Global end of trial reached?	Yes
Global end of trial date	01 April 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective is to minimize fluid reaccumulation in the hepatic cyst after aspiration sclerotherapy in order to reduce cyst size.

Protection of trial subjects:

Ethical approval of the study protocol was given by the Central Committee on Research Involving Human Subjects and by the local accredited Medical Research Ethics Committee of the region Arnhem-Nijmegen, the Netherlands (reference number: 2013/354).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2013
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	Netherlands: 34
Worldwide total number of subjects	34
EEA total number of subjects	34

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)	30
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

During a 4 week screening period patients were screened based on the inclusion and exclusion criteria

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Pasireotide treatment

Arm description:

pasireotide treatment long-acting release, 60 mg injection

Arm type	Experimental
Investigational medicinal product name	pasireotide (long-acting release, 60 mg injection)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection

Dosage and administration details:

pasireotide (long-acting release, 60 mg injection) two weeks prior to and two weeks following aspiration sclerotherapy

Arm title	Placebo
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Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection

Dosage and administration details:

placebo

Number of subjects in period 1	Pasireotide treatment	Placebo
Started	17	17
Completed	17	17

Baseline characteristics

End points

End points reporting groups

Reporting group title	Pasireotide treatment
Reporting group description:	
pasireotide treatment long-acting release, 60 mg injection	
Reporting group title	Placebo
Reporting group description:	-

Primary: Mean proportional change (%) in cyst diameter

End point title	Mean proportional change (%) in cyst diameter
End point description:	
End point type	Primary
End point timeframe:	
four weeks after AS	

End point values	Pasireotide treatment	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	17		
Units: % cyst diameter	17	17		

Statistical analyses

Statistical analysis title	Intention-to-treat (ITT) analyses
Comparison groups	Pasireotide treatment v Placebo
Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Mean proportional change

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious adverse events <24 hours

Adverse events

Assessment type	Systematic
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Dictionary used

Dictionary name	WHO-ART
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Dictionary version	1
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Reporting groups

Reporting group title	Pasireotide treatment
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Reporting group description: -

Serious adverse events	Pasireotide treatment		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 17 (11.76%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Respiratory, thoracic and mediastinal disorders			
Pneumoniae/pneumonitis			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Urolithiasis			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Pasireotide treatment		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 17 (100.00%)		
Endocrine disorders			

Hyperglycaemia subjects affected / exposed occurrences (all)	17 / 17 (100.00%) 17		
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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