Clinical trial results:
Determination of radiation dose for the bile acid tracer 11C-CSar in humans

Summary

EudraCT number	2016-004031-20
Trial protocol	DK
Global end of trial date	26 March 2018

Results information

Result version number	v1 (current)
This version publication date	26 December 2020
First version publication date	26 December 2020

Trial information

Trial identification

Sponsor protocol code	0090

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Aarhus University Hospital
Sponsor organisation address	Palle Juul-Jensens Boulevard 99, Aarhus N, Denmark, 8200
Public contact	senior lecturer, Aarhus University Hospital, 45 30939936, susakeid@clin.au.dk
Scientific contact	senior lecturer, Aarhus University Hospital, 45 30939936, susakeid@clin.au.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	26 March 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 March 2018
Global end of trial reached?	Yes
Global end of trial date	26 March 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of the trial is to define biodistribution of 11C-CSar in the human body in healthy subjects and patients with cholestatic liver disease and to estimate equivalent dose exposure.

Protection of trial subjects:

This study conformed to the standards of conduct for clinical studies as set forth in the Declaration of Helsinki and the legal regulations in Denmark. International Conference on Harmonization (ICH) guidelines for good clinical practices (GCP) was followed. After written approval from the Independent Ethics Committee (IEC) and competent authority has been obtained, the Investigator obtained informed consent from the subject's legally acceptable representative.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 December 2016
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	Denmark: 9
Worldwide total number of subjects	9
EEA total number of subjects	9

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)	6
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

6 healthy subjects included were screened for no liver disease. 3 patients were included from out-patients clinic, two with primary biliary cholangitis and one with primary sclerosing cholangitis - under standard medical treatment.

Pre-assignment period milestones

Number of subjects started	9
Number of subjects completed	8

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Consent withdrawn by subject: 1

Period 1

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

Arms

Arm title	PET-scanning with bile acid tracer

Arm description:

Subjects were examined by wholebody PET-scan with 11C-CSar bile acid tracer and a blood-sample to dertermine bile acid concentration.

Arm type	Experimental
Investigational medicinal product name	11C-cholylsarcosine
Investigational medicinal product code	V09DX
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

60-143 MBq megabecquerel(s) Intravenous bolus use

Number of subjects in period 1[1]	PET-scanning with bile acid tracer
Started	8
Completed	8

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: There was one withdrawn participant.

Baseline characteristics

Reporting groups

Reporting group title	Overall period

Reporting group description: -

Reporting group values	Overall period	Total	
Number of subjects	8	8	
Age categorical 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)	6	6	
From 65-84 years	2	2	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	60		
full range (min-max)	34 to 73	-	
Gender categorical Units: Subjects			
Female	4	4	
Male	4	4	

End points

End points reporting groups

Reporting group title	PET-scanning with bile acid tracer

Reporting group description:

Subjects were examined by wholebody PET-scan with 11C-CSar bile acid tracer and a blood-sample to dertermine bile acid concentration.

Primary: Gender-averaged effective dose (healthy)

End point title	Gender-averaged effective dose (healthy)[1]

End point description:

End point type	Primary

End point timeframe:

The endpoint analyzed within three days of the examination. Measurable unit were: microSv/MBq

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: For statistical analysis, see linked publication

End point values	PET-scanning with bile acid tracer			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: sievert				
arithmetic mean (standard deviation)	6.2 (± 1.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Gender-averaged effective dose (healthy)

End point title	Gender-averaged effective dose (healthy)[2]

End point description:

End point type	Primary

End point timeframe:

The endpoint analyzed within three days of the examination. Measurable unit were: microSv/MBq

Notes:

[2] - 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: For statistical analysis, see linked publication

End point values	PET-scanning with bile acid tracer			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: sievert				
arithmetic mean (standard deviation)	6.1 (± 1.2)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Adverse Events were collected during the whole study. No adverse events were reported.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	13

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

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: No adverse events (non-serious or serious) were reported.

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/31330413