Clinical trial results:
Test of reliability of PET-rubidium82-scan in determination of renal blood flow in healthy subjects

Summary

EudraCT number	2017-005008-88
Trial protocol	DK
Global end of trial date	11 March 2019

Results information

Result version number	v1 (current)
This version publication date	09 October 2020
First version publication date	09 October 2020

Trial information

Trial identification

Sponsor protocol code	SL-2-2017

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medicinsk Forskning
Sponsor organisation address	Lægårdvej 12, Holstebro, Denmark, 7500
Public contact	Stine Langaa, Medicinsk Forskning, Regionshospitalet Holstebro, Hospitalsenheden Vest, 0045 78436587, stinlg@rm.dk
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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	07 July 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 March 2019
Global end of trial reached?	Yes
Global end of trial date	11 March 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To test the reliability PET-rubium-82-scans in regards to determination of renal blood flow

Protection of trial subjects:

No specific measures were put in place

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 September 2018
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: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	10
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited by advertisement in the local newspaper

Pre-assignment

Screening details:

Prior to inclusion, each participant completed a screening program. Screening consisted of a medical history; a clinical examination including measurements of weight, height, and blood pressure; electrocardiography; blood tests; urine dipstick

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	Two examination days

Arm description:

Subjects were scanned on two separate days. On one day a single scan was performed. On another day a scan was performed before and after a 2-hour long amino acid-infusion

Arm type	order of examination days
Investigational medicinal product name	Rubidium-cloride-82
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Radionuclide generator
Routes of administration	Intravenous bolus use

Dosage and administration details:

555 MBq. pr. bolus injection. 3 injections in total

Number of subjects in period 1	Two examination days
Started	20
Completed	17
Not completed	3
Consent withdrawn by subject	3

Baseline characteristics

Reporting groups	
Reporting group title	Overall period

Reporting group description: -

Reporting group values	Overall period	Total	
Number of subjects	20	20	
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)	10	10	
From 65-84 years	10	10	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	9	9	
Male	11	11	

End points

End points reporting groups

Reporting group title	Two examination days

Reporting group description:

Subjects were scanned on two separate days. On one day a single scan was performed. On another day a scan was performed before and after a 2-hour long amino acid-infusion

Primary: Unstimulated K1 - right kidney

End point title	Unstimulated K1 - right kidney[1]

End point description:

K1 is calculated for each kidney using the abdominal aorta as input function in the 1-tissue compartment model

End point type	Primary

End point timeframe:

At the end of the trial when all subjects have completed the days of examination

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: Data is presented as mean +/- standard deviation

End point values	Two examination days			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: ml/min/g				
arithmetic mean (standard deviation)	1.2871 (± 0.141)			

Statistical analyses

No statistical analyses for this end point

Primary: Unstimulated K1 - left kidney

End point title	Unstimulated K1 - left kidney[2]

End point description:

K1 is calculated for each kidney using the abdominal aorta as input function in the 1-tissue compartment model

End point type	Primary

End point timeframe:

At the end of the trial when all subjects have completed the days of examination

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: Data is presented as mean +/- standard deviation

End point values	Two examination days			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: ml/min/g				
arithmetic mean (standard deviation)	1.2766 (± 0.155)			

Statistical analyses

No statistical analyses for this end point

Primary: Stimulated K1 - right kidney

End point title	Stimulated K1 - right kidney[3]

End point description:

K1 is calculated for each kidney using the abdominal aorta as input function in the 1-tissue compartment model

End point type	Primary

End point timeframe:

At the end of the trial when all subjects have completed the days of examination

Notes:

[3] - 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: Data is presented as mean +/- standard deviation

End point values	Two examination days			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: ml/min/g				
arithmetic mean (standard deviation)	1.4220 (± 0.214)			

Statistical analyses

No statistical analyses for this end point

Primary: Stimulated K1 - left kidney

End point title	Stimulated K1 - left kidney[4]

End point description:

K1 is calculated for each kidney using the abdominal aorta as input function in the 1-tissue compartment model

End point type	Primary

End point timeframe:

At the end of the trial when all subjects have completed the days of examination

Notes:

[4] - 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: Data is presented as mean +/- standard deviation

End point values	Two examination days			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: ml/min/g				
arithmetic mean (standard deviation)	1.4107 (± 0.212)			

Statistical analyses

No statistical analyses for this end point

Secondary: Day-to-day variation - right kidney

End point title	Day-to-day variation - right kidney

End point description:

End point type	Secondary

End point timeframe:

At the end of the trial when all subjects have completed the days of examination

End point values	Two examination days			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: Percent				
number (not applicable)	6.0			

Statistical analyses

No statistical analyses for this end point

Secondary: Day-to-day variation - left kidney

End point title	Day-to-day variation - left kidney

End point description:

End point type	Secondary

End point timeframe:

At the end of the trial when all subjects have completed the days of examination

End point values	Two examination days			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: percent				
number (not applicable)	6.4			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
For each subject: From the first injection untill the last injection has been given	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21

Reporting groups	
Reporting group title	Examination days

Reporting group description: -

Serious adverse events	Examination days		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 17 (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	Examination days		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 17 (5.88%)		
Cardiac disorders			
Dizzyness	Additional description: Mild dizzyness and discomfort after completion of the second scan on day B. Was probably due to a fasting period prior to and during the scans.		
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		

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