Clinical trial results:
Determination of renal blood flow based on Rubidium-82 and PET-technology in healthy volunteers

Summary

EudraCT number	2016-004080-39
Trial protocol	DK
Global end of trial date	28 May 2018

Results information

Result version number	v1
This version publication date	09 October 2020
First version publication date	09 October 2020

Trial information

Trial identification

Sponsor protocol code	SL-1-2016

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
Scientific contact	Jesper Nørgaard Bech, Medicinsk Forskning, Regionshospitalet Holstebro, Hospitalsenheden Vest, 78436587 78436787, jesper.noergaard.bech@vest.rm.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	17 June 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 May 2018
Global end of trial reached?	Yes
Global end of trial date	28 May 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To develop a new and reliable method to determine renal blood flow based on Rubidium-82 and PET-technology using a 1-tissue compartment model

Protection of trial subjects:

No specific measures

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 October 2017
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)	20
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited by advertisement, primarily at local educational institutions.

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 bed positions

Arm description:

Subjects were scanned in two different bed positions and hereby in two different fields of view.

Arm type	Scan order
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. 4 bolus injections in total

Number of subjects in period 1	Two bed positions
Started	20
Completed	18
Not completed	2
Consent withdrawn by subject	2

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)	20	20	
From 65-84 years	0	0	
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 bed positions

Reporting group description:

Subjects were scanned in two different bed positions and hereby in two different fields of view.

Primary: K1 - right kidney - Input function: Left ventricular blood pool

End point title	K1 - right kidney - Input function: Left ventricular blood pool[1]

End point description:

K1 is determined for each kidney using different input functions in the 1-tissue compartment model (the left ventricular blood pool and the abdominal aorta). AA is used as input function in two different fields of view (FOVs). FOVA and FOVB.

End point type	Primary

End point timeframe:

At the end of the trial when all subjects have completed the day 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 +/- the standard deviation

End point values	Two bed positions			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: ml/min/g				
arithmetic mean (standard deviation)	2.025 (± 0.305)			

Statistical analyses

No statistical analyses for this end point

Primary: K1 - left kidney - Input function: Left ventricular blood pool

End point title	K1 - left kidney - Input function: Left ventricular blood pool[2]

End point description:

K1 is determined for each kidney using different input functions in the 1-tissue compartment model (the left ventricular blood pool and the abdominal aorta). AA is used as input function in two different fields of view (FOVs). FOVA and FOVB.

End point type	Primary

End point timeframe:

At the end of the trial when all subjects have completed the day 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 +/- the standard deviation

End point values	Two bed positions			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: ml/min/g				
arithmetic mean (standard deviation)	2.001 (± 0.309)			

Statistical analyses

No statistical analyses for this end point

Primary: K1 - right kidney - Input function: Abdominal aorta. FOVA

End point title	K1 - right kidney - Input function: Abdominal aorta. FOVA[3]

End point description:

K1 is determined for each kidney using different input functions in the 1-tissue compartment model (the left ventricular blood pool and the abdominal aorta). AA is used as input function in two different fields of view (FOVs). FOVA and FOVB.

End point type	Primary

End point timeframe:

At the end of the trial when all subjects have completed the day 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 +/- the standard deviation

End point values	Two bed positions			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: ml/min/g				
arithmetic mean (standard deviation)	2.086 (± 0.348)			

Statistical analyses

No statistical analyses for this end point

Primary: K1 - left kidney - Input function: abdominal aorta. FOVA

End point title	K1 - left kidney - Input function: abdominal aorta. FOVA[4]

End point description:

K1 is determined for each kidney using different input functions in the 1-tissue compartment model (the left ventricular blood pool and the abdominal aorta). AA is used as input function in two different fields of view (FOVs). FOVA and FOVB.

End point type	Primary

End point timeframe:

At the end of the trial when all subjects have completed the day 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 bed positions			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: ml/min/g				
arithmetic mean (standard deviation)	2.059 (± 0.330)			

Statistical analyses

No statistical analyses for this end point

Primary: K1 - right kidney - Input function: Abdominal aorta. FOVB

End point title	K1 - right kidney - Input function: Abdominal aorta. FOVB[5]

End point description:

K1 is determined for each kidney using different input functions in the 1-tissue compartment model (the left ventricular blood pool and the abdominal aorta). AA is used as input function in two different fields of view (FOVs). FOVA and FOVB.

End point type	Primary

End point timeframe:

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

Notes:

[5] - 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 +/- the standard deviation

End point values	Two bed positions			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: ml/min/g				
arithmetic mean (standard deviation)	2.055 (± 0.328)			

Statistical analyses

No statistical analyses for this end point

Primary: K1 - left kidney - Input function: abdominal aorta. FOVB

End point title	K1 - left kidney - Input function: abdominal aorta. FOVB[6]

End point description:

K1 is determined for each kidney using different input functions in the 1-tissue compartment model (the left ventricular blood pool and the abdominal aorta). AA is used as input function in two different fields of view (FOVs). FOVA and FOVB.

End point type	Primary

End point timeframe:

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

Notes:

[6] - 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 +/- the standard deviation

End point values	Two bed positions			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: ml/min/g				
arithmetic mean (standard deviation)	2.034 (± 0.303)			

Statistical analyses

No statistical analyses for this end point

Secondary: Intra-assay coefficient of variation. Renal blood flow (K1) - right kidney - inout function: Left ventricular blood pool

End point title	Intra-assay coefficient of variation. Renal blood flow (K1) - right kidney - inout function: Left ventricular blood pool

End point description:

K1 is determined for each kidney using different input functions in the 1-tissue compartment model (the left ventricular blood pool and the abdominal aorta). AA is used as input function in two different fields of view (FOVs). FOVA and FOVB. Intra-assay coefficients of variation were calculated for each input function for each kidney based on duplicate K1 determinations in each FOV.

End point type	Secondary

End point timeframe:

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

End point values	Two bed positions			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: percent				
number (not applicable)	5.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Intra-assay coefficient of variation. left kidney - input function: Left ventricular blood pool

End point title	Intra-assay coefficient of variation. left kidney - input function: Left ventricular blood pool

End point description:

K1 is determined for each kidney using different input functions in the 1-tissue compartment model (the left ventricular blood pool and the abdominal aorta). AA is used as input function in two different fields of view (FOVs). FOVA and FOVB. Intra-assay coefficients of variation were calculated for each input function for each kidney based on duplicate K1 determinations in each FOV.

End point type	Secondary

End point timeframe:

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

End point values	Two bed positions			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: percent				
number (not applicable)	5.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Intra-assay coefficient of variation. right kidney - input function: abdominal aorta. FOVA

End point title	Intra-assay coefficient of variation. right kidney - input function: abdominal aorta. FOVA

End point description:

K1 is determined for each kidney using different input functions in the 1-tissue compartment model (the left ventricular blood pool and the abdominal aorta). AA is used as input function in two different fields of view (FOVs). FOVA and FOVB. Intra-assay coefficients of variation were calculated for each input function for each kidney based on duplicate K1 determinations in each FOV.

End point type	Secondary

End point timeframe:

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

End point values	Two bed positions			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: percent				
number (not applicable)	4.5			

Statistical analyses

No statistical analyses for this end point

Secondary: Intra-assay coefficient of variation. left kidney - input function: abdominal aorta. FOVA

End point title	Intra-assay coefficient of variation. left kidney - input function: abdominal aorta. FOVA

End point description:

K1 is determined for each kidney using different input functions in the 1-tissue compartment model (the left ventricular blood pool and the abdominal aorta). AA is used as input function in two different fields of view (FOVs). FOVA and FOVB. Intra-assay coefficients of variation were calculated for each input function for each kidney based on duplicate K1 determinations in each FOV.

End point type	Secondary

End point timeframe:

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

End point values	Two bed positions			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: percent				
number (not applicable)	4.2			

Statistical analyses

No statistical analyses for this end point

Secondary: Intra-assay coefficient of variation. right kidney - input function: abdominal aorta. FOVB

End point title	Intra-assay coefficient of variation. right kidney - input function: abdominal aorta. FOVB

End point description:

K1 is determined for each kidney using different input functions in the 1-tissue compartment model (the left ventricular blood pool and the abdominal aorta). AA is used as input function in two different fields of view (FOVs). FOVA and FOVB. Intra-assay coefficients of variation were calculated for each input function for each kidney based on duplicate K1 determinations in each FOV.

End point type	Secondary

End point timeframe:

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

End point values	Two bed positions			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: percent				
number (not applicable)	4.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Intra-assay coefficient of variation. left kidney - input function: abdominal aorta. FOVB

End point title	Intra-assay coefficient of variation. left kidney - input function: abdominal aorta. FOVB

End point description:

K1 is determined for each kidney using different input functions in the 1-tissue compartment model (the left ventricular blood pool and the abdominal aorta). AA is used as input function in two different fields of view (FOVs). FOVA and FOVB. Intra-assay coefficients of variation were calculated for each input function for each kidney based on duplicate K1 determinations in each FOV.

End point type	Secondary

End point timeframe:

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

End point values	Two bed positions			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: Percent				
number (not applicable)	4.5			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

For each participant: From the first injection of Rb-82 till 48 hours after the last injection.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21

Reporting groups

Reporting group title	Two bed positions

Reporting group description: -

Serious adverse events	Two bed positions		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 18 (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	Two bed positions		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 18 (0.00%)		

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 non-serious adverse events were recorded

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