



Clinical trial results:

MET-PET-study - Comparative study of Tc-99m- sestamibi SPECT/IdCT with C-11-L-Methionin PET/diagnostic CT and theri ability to locate paratyroid adenomas preoperatively.

Summary

EudraCT number	2013-004886-14
Trial protocol	DK
Global end of trial date	13 July 2020

Results information

Result version number	v1 (current)
This version publication date	01 July 2023
First version publication date	01 July 2023

Trial information

Trial identification

Sponsor protocol code	2013092981
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Dep. Nuclear medicine, Odense univeristy hospital
Sponsor organisation address	Kløvervænget 17, Odense, Denmark, 5000
Public contact	sys.vestergaard@rsyd.dk, Dep.nuclear medicine, Odense university hospital, 45 65412980, sys.vestergaard@rsyd.dk
Scientific contact	sys.vestergaard@rsyd.dk, Dep.nuclear medicine, Odense university hospital, 45 65412980, sys.vestergaard@rsyd.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	06 March 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 July 2020
Global end of trial reached?	Yes
Global end of trial date	13 July 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

MET-PET-study - Comparative study of Tc-99m- sestamibi SPECT/IdCT with C-11-L-Methionine PET/diagnostic CT and their ability to locate hyperfunctioning parathyroid tissue preoperatively in suspected primary hyperparathyroidism.

Protection of trial subjects:

Routine care

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 April 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: 27
Worldwide total number of subjects	27
EEA total number of subjects	27

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)	19
From 65 to 84 years	8
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

adult patients diagnosed with primary hyperparathyroidism referred to preoperative localization of potential hyperfunctioning parathyroid tissue.

Pre-assignment

Screening details:

Patients diagnosed with primary hyperparathyroidism referred to surgical removal of hyperfunctioning parathyroid tissue

Period 1

Period 1 title	Technetium 99m Sestamibi
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Sestamibi
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Arm description:

Conventional parathyroid scintigraphy

Arm type	Active comparator
Investigational medicinal product name	TECHNETIUM (99MTC) SESTAMIBI
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Up to 700 MBq megabecquerel(s)

Number of subjects in period 1	Sestamibi
Started	27
Completed	27

Period 2

Period 2 title	C-11-Methionine
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Methionin
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	C-11-L-Methionin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

420 to 560 MBq megabecquerel(s)

Number of subjects in period 2	Methionin
Started	27
Completed	27

Baseline characteristics

Reporting groups

Reporting group title	Sestamibi
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Reporting group description:

Conventional parathyroid scintigraphy

Reporting group values	Sestamibi	Total	
Number of subjects	27	27	
Age categorical			
> Men and women over the age of 18 yr			
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)	19	19	
From 65-84 years	8	8	
85 years and over	0	0	
Gender categorical			
Men and women			
Units: Subjects			
Female	18	18	
Male	9	9	

Subject analysis sets

Subject analysis set title	localisation of adenoma
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Subject analysis set type	Modified intention-to-treat
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Subject analysis set description:

Patients referred to surgical treatment of primary hyperparathyroidism referred to preoperative localization having performed both our conventional parathyroid scintigraphy and Methionin PET/CT.

Reporting group values	localisation of adenoma		
Number of subjects	27		
Age categorical			
> Men and women over the age of 18 yr			
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)	19		
From 65-84 years	8		
85 years and over	0		
Gender categorical			
Men and women			
Units: Subjects			
Female	19		
Male	8		

End points

End points reporting groups

Reporting group title	Sestamibi
Reporting group description: Conventional parathyroid scintigraphy	
Reporting group title	Methionin
Reporting group description: -	
Subject analysis set title	localisation of adenoma
Subject analysis set type	Modified intention-to-treat
Subject analysis set description: Patients referred to surgical treatment of primary hyperparathyroidism referred to preoperative localization having performed both our conventional parathyroid scintigraphy and Methionin PET/CT.	

Primary: Primary endpoints

End point title	Primary endpoints
End point description: Detection of adenomas in each of the two scanning modalities performed in each patient, compared to the peroperative findings including histopathologic findings and verified with postoperative blood sample controls.	
End point type	Primary
End point timeframe: 12 months	

End point values	Sestamibi	Methionin	localisation of adenoma	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	27	27	27	
Units: hyperplastic parathyroid tissue				
adenoma	19	19	19	
hyperplastic tissue	8	8	8	

Statistical analyses

Statistical analysis title	Comparable
Statistical analysis description: Identification of adenomas and/or hyperplasia versus normal histology was analyzed on a per-lesion basis by sensitivity, specificity, PPV, NPV and accuracy.	
Comparison groups	Sestamibi v Methionin
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.24
Method	Chi-squared
Parameter estimate	Mean difference (final values)
Point estimate	-0.11

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.29
upper limit	0.08
Variability estimate	Standard error of the mean
Dispersion value	0.091837

Secondary: Secondary end points

End point title	Secondary end points
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End point description:

The ability of the two imaging modalities to correctly localize the hyperfunctioning parathyroid tissue on a phantom drawing of the thyroid divided into 3 sites on each side, one at isthmus and 3 sites for ectopic localization at caput, collum or thorax and lastly the opportunity of nothing localized.
The certainty of detection or no detection on a likert scale from 1-5.

End point type	Secondary
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End point timeframe:

12 months

End point values	localisation of adenoma			
Subject group type	Subject analysis set			
Number of subjects analysed				
Units: Likert				
number (not applicable)				
Likert	27			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

May 4 2016 - March 21 2020

Assessment type	Non-systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	4
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Reporting groups

Reporting group title	27 patients
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Reporting group description:

Out of 27 patients having two imaging examinations performed, only one patient developed one incidence of urticaria due to physical pressure on the tissue, to which the patient was known to prior to inclusion.

Serious adverse events	27 patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0.04 %

Non-serious adverse events	27 patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)		
Skin and subcutaneous tissue disorders			
Urticaria pressure	Additional description: Known condition.		
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 March 2017	Due to lack of operation tables, the time from completed last scan to completed operation was increased from 2 month to 12 month.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Due to the long inclusionfase, it was difficult to obtain skills assessing the non-conventional imaging scans which can have been a drawback compared to the conventional modality.

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/36881250>