Clinical trial results:
18F-FDG-WBC-PET/CT for PJI and after uneventful prosthesis surgery

Summary

EudraCT number	2013-001607-36
Trial protocol	SE
Global end of trial date	07 August 2020

Results information

Result version number	v1 (current)
This version publication date	15 May 2021
First version publication date	15 May 2021

Trial information

Trial identification

Sponsor protocol code	1

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Region Stockholm
Sponsor organisation address	Lindhagensgatan 98, Stockholm, Sweden,
Public contact	Annette Fransson-Andreo, verksamhetschef, Region Stockholm, annette.fransson-andreo-hernandez@sll.se
Scientific contact	Rimma Axelsson, professor, Region Stockholm, rimma.axelsson@sll.se

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 August 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 July 2020
Global end of trial reached?	Yes
Global end of trial date	07 August 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Evaluate the accuracy, sensitivity and specificity of 18F-FDG-WBC-PET/CT combined with Tc99m-Nanocolloid scintigraphy for the diagnosis of PJI as well as evaluate the uptake of 18F-FDG-WBC-PET/CT after uneventful prosthesis surgery.

Protection of trial subjects:

Monitoring of HR, BT and RF before and after examination.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 2013
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	Sweden: 28
Worldwide total number of subjects	28
EEA total number of subjects	28

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)	7
From 65 to 84 years	21
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Patients with suspected PJI in the suitable age range were asked for inclusion in the infection part of the study. Random patients with previous hip surgery were asked for inclusion in the uneventful part of the study.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Single blind[1]
Roles blinded	Investigator, Data analyst[2]

Blinding implementation details:

Blinding was only used for the evaluation of the images, the participants were not blinded.

Arms

Are arms mutually exclusive?	Yes
Arm title	Infection arm

Arm description:

All patients with suspected PJI included in the study

Arm type	Experimental
Investigational medicinal product name	18F-FDG-WBC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

Autologous leukocytes were separated from the patients blood, radiolabelled with 18F-FDG and reinjected if the activity was below 600 MBq.

Arm title	Uneventful arm

Arm description:

All patients without suspicion of infection

Arm type	Experimental
Investigational medicinal product name	18F-FDG-WBC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

Autologous leukocytes were separated from the patients blood, radiolabelled with 18F-FDG and reinjected if the activity was below 600 MBq.

Notes:

[1] - The number of roles blinded appears inconsistent with a single blinded trial. It is expected that there will be one role blinded in a single blind trial.
Justification: The trial is not a drug trial but an evaluation of the images obtained using the radiopharmaceutical. Only the analyst of the images were blinded.
[2] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: The trial is not a drug trial but an evaluation of the images obtained using the radiopharmaceutical. Only the analyst of the images were blinded.

Number of subjects in period 1	Infection arm	Uneventful arm
Started	20	8
Completed	19	8
Not completed	1	0
Death during follow-up, unrelated	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Infection arm
Reporting group description:	
All patients with suspected PJI included in the study	
Reporting group title	Uneventful arm
Reporting group description:	
All patients without suspicion of infection	

Reporting group values	Infection arm	Uneventful arm	Total
Number of subjects	20	8	28
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	7	0	7
From 65-84 years	13	8	21
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	7	4	11
Male	13	4	17

End points

End points reporting groups

Reporting group title	Infection arm
Reporting group description:	
All patients with suspected PJI included in the study	
Reporting group title	Uneventful arm
Reporting group description:	
All patients without suspicion of infection	

Primary: Specificity

End point title	Specificity[1][2]
End point description:	
End point type	Primary
End point timeframe:	
At 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: All patients in the arm underwent both examination types. McNemar's test was used to compare them. It is not possible to enter this data on the site.
[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only the infection arm is used for this endpoint.

End point values	Infection arm			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: 0-100	19			

Statistical analyses

No statistical analyses for this end point

Primary: Uptake

End point title	Uptake[3][4]
End point description:	
Visual evaluation of the distribution of uptake surrounding the prosthesis	
End point type	Primary
End point timeframe:	
At 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: Only the uneventful arm is used for this end point.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The comparison is between subjects in the arm at different time points to show correlation between time and uptake. It is not possible to enter this data on the site.

End point values	Uneventful arm			
Subject group type	Reporting group			
Number of subjects analysed	8[5]			
Units: visual evaluation				
number (not applicable)	8			

Notes:

[5] - Repeated measurements in some cases

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: The hours surrounding the examination.	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	10.0
Reporting groups	
Reporting group title	Infection arm
Reporting group description: All patients with suspected PJI included in the study	
Reporting group title	Uneventful arm
Reporting group description: All patients without suspicion of infection	

Serious adverse events	Infection arm	Uneventful arm	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	0 / 8 (0.00%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Infection arm	Uneventful arm	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 20 (30.00%)	6 / 8 (75.00%)	
Vascular disorders			
Increased blood pressure			
subjects affected / exposed	1 / 20 (5.00%)	5 / 8 (62.50%)	
occurrences (all)	1	5	
Cardiac disorders			
Increased heart rate			
subjects affected / exposed	4 / 20 (20.00%)	3 / 8 (37.50%)	
occurrences (all)	4	3	
Respiratory, thoracic and mediastinal disorders			

Increased respiratory rate subjects affected / exposed occurrences (all)	4 / 20 (20.00%) 4	0 / 8 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 March 2015	The Infection arm changed from two independent arms to examining the first 20 patients with both examinations.
10 August 2017	The last patients in the uneventful arm changed from being examined at 3, 6 and 12 months to being examined at 24 months after the operation.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported