



Clinical trial results:

16-18F-fluor-17-estradiol PET/CT for detection of estrogen receptor positive liver metastases in breast cancer

Summary

EudraCT number	2019-002665-35
Trial protocol	DK
Global end of trial date	04 October 2024

Results information

Result version number	v1 (current)
This version publication date	02 November 2024
First version publication date	02 November 2024

Trial information

Trial identification

Sponsor protocol code	190619
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04150731
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Aarhus University Hospytal
Sponsor organisation address	Palle Juul Jensens Boulevard 99, Aarhus, Denmark, 8200
Public contact	Mette Abildgaard Pedersen, Aarhus University Hospital, +45 31411180, meabpe@biomed.au.dk
Scientific contact	Mette Abildgaard Pedersen, Aarhus University Hospital, +45 31411180, meabpe@biomed.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	04 October 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 October 2024
Global end of trial reached?	Yes
Global end of trial date	04 October 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate parametric and conventional FES-PET/CT as methods of quantification of estrogen receptor (ER) expression in patients with disseminated BC

Protection of trial subjects:

GCP trail unit Aarhus University

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 October 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 8
Worldwide total number of subjects	8
EEA total number of subjects	8

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	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

At oncology department , Aarhus University Hospital

Pre-assignment

Screening details:

Inclusion criteria: metastatic ER+, human epidermal growth factor receptor 2 negative (HER2-) BC (2) at least two liver metastases visualized on CT (3) treatment with aromatase inhibitors or chemotherapy (4) postmenopausal status.

Period 1

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

Arms

Arm title	FES SCAN
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	18F-Fluoroestradiol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

200 MBq

Number of subjects in period 1	FES SCAN
Started	8
Completed	8

Baseline characteristics

Reporting groups

Reporting group title	Overall trial
Reporting group description: -	

Reporting group values	Overall trial	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			
median	57		
full range (min-max)	41 to 74	-	
Gender categorical			
Units: Subjects			
Female	8	8	
Male	0	0	

Subject analysis sets

Subject analysis set title	FES uptake
Subject analysis set type	Full analysis

Subject analysis set description:

Tumor to background FES uptake was increased with dynamic imaging compared to static imaging.

Subject analysis set title	FES Uptake Patlak
Subject analysis set type	Full analysis

Subject analysis set description:

FES Uptake Patlak

Reporting group values	FES uptake	FES Uptake Patlak	
Number of subjects	8	8	
Age categorical			
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)	6		
From 65-84 years	2		
85 years and over	0		
Age continuous			
Units: years			
median	57		
full range (min-max)	41 to 74		
Gender categorical			
Units: Subjects			
Female	8		
Male	0		

End points

End points reporting groups

Reporting group title	FES SCAN
Reporting group description: -	
Subject analysis set title	FES uptake
Subject analysis set type	Full analysis
Subject analysis set description:	
Tumor to background FES uptake was increased with dynamic imaging compared to static imaging.	
Subject analysis set title	FES Uptake Patlak
Subject analysis set type	Full analysis
Subject analysis set description:	
FES Uptake Patlak	

Primary: FES tumor to background

End point title	FES tumor to background
End point description:	
Tumor to background FES uptake was increased with dynamic imaging compared to static imaging.	
End point type	Primary
End point timeframe:	
2023	

End point values	FES uptake	FES Uptake Patlak		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8	8		
Units: ratio				
arithmetic mean (standard deviation)	2.45 (\pm 0.2)	0 (\pm 0)		

Statistical analyses

Statistical analysis title	t-test
Comparison groups	FES uptake v FES Uptake Patlak
Number of subjects included in analysis	16
Analysis specification	Pre-specified
Analysis type	other ^[1]
P-value	< 0.05
Method	t-test, 2-sided

Notes:

[1] - t-test

Adverse events

Adverse events information

Timeframe for reporting adverse events:

1 adverse event with back pain

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22.0
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Reporting groups

Reporting group title	FES exposure
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Reporting group description: -

Serious adverse events	FES exposure		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 8 (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 %

Non-serious adverse events	FES exposure		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 8 (12.50%)		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 8 (12.50%)		
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