Clinical trial results:
Dynamics and tracer distribution of Tilmanocept using combined subareolar and peritumoral injection technique for scintigraphic sentinel lymph node detection in early stage breast cancer.

Summary

EudraCT number	2019-002597-32
Trial protocol	BE
Global end of trial date	05 January 2021

Results information

Result version number	v1 (current)
This version publication date	20 March 2022
First version publication date	20 March 2022
Summary attachment (see zip file)	BC5331_EudraCT_Statement of discontinuation (BC5331_EudraCT_Statement of discontinuation.pdf)

Trial information

Trial identification

Sponsor protocol code	AGO/2019/003

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Ghent University Hospital
Sponsor organisation address	Corneel Heymanslaan 10, Ghent, Belgium, 9000
Public contact	HIRUZ CTU, University Hospital Ghent, +32 9 3320500, leen.geets@uzgent.be
Scientific contact	HIRUZ CTU, University Hospital Ghent, +32 9 3320500, leen.geets@uzgent.be

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	05 January 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	05 January 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Documenting the distribution of 99m-Tc Tilmanocept at multiple timepoints post-injection (combined peritumoral and subareolar) and comparing this data with the distribution of 99m-Tc nanocoll at the same timepoints.

Protection of trial subjects:

Ethics review and approval, informed consent, supportive care and routine monitoring.

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	01 October 2019
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	Belgium: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

99999 is "Not applicable" value or 0 participants.

Pre-assignment

Screening details:

Inclusion:
- Women with newly diagnosed stage 1 or 2 breast cancer
- Clinically “node negative” (no clinically enlarged lymph nodes)
- Equal or more than 18 years old

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Assessor

Arms

Are arms mutually exclusive?	No
Arm title	99m-Technetium-Tilmanocept

Arm description: -

Arm type	Experimental
Investigational medicinal product name	99m-Technetium-Tilmanocept
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Radiopharmaceutical precursor, solution
Routes of administration	Injection

Dosage and administration details:

74MBq divided over 2 doses of 0,5mL each

Arm title	99m-Technetium-albumine nanocolloid

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	99m-technetium-albumine-nanocolloid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Radiopharmaceutical precursor, solution
Routes of administration	Injection

Dosage and administration details:

74MBq divided over 2 doses of 0,5mL each

Number of subjects in period 1	99m-Technetium-Tilmanocept	99m-Technetium-albumine nanocolloid
Started	99999	99999
Completed	99999	99999

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	99999	99999	
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)	99999	99999	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	99m-Technetium-Tilmanocept
Reporting group description: -	
Reporting group title	99m-Technetium-albumine nanocolloid
Reporting group description: -	

Primary: Distribution pattern analysed

End point title	Distribution pattern analysed[1]
End point description:	
End point type	Primary
End point timeframe: after 24 hours	

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: No statistical analysis done as no patients have been recruited for this study

End point values	99m-Technetium-Tilmanocept	99m-Technetium-albumine nanocolloid		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	99999	99999		
Units: patients				
pattern analysed	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
Overall study	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	24

Frequency threshold for reporting non-serious adverse events: 0 %

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 adverse events have been reported as no patients have been recruited

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