



Clinical trial results:

Prospective phase II pilot study, assessing imaging performance of 89Zirconium-labelled Girentuximab (89Zr-TLX250) PET-CT in metastatic triple negative breast cancer patients

OPADESCENCE: zircon PET-CT imaging TLX metastatic triple Negative Cancer

Summary

EudraCT number	2020-003805-71
Trial protocol	FR
Global end of trial date	13 September 2023

Results information

Result version number	v1 (current)
This version publication date	08 July 2026
First version publication date	08 July 2026

Trial information

Trial identification

Sponsor protocol code	ICO-2020-25
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04758780
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	INSTITUT DE CANCEROLOGIE DE L'OUEST
Sponsor organisation address	Boulevard Jacques Monod, SAINT HERBLAIN, France, 44800
Public contact	Clinical Research Dept- Promotion R, INSTITUT DE CANCEROLOGIE DE L'OUEST, +33 240679900, promotionrc@ico.unicancer.fr
Scientific contact	Clinical Research Dept- Promotion R, INSTITUT DE CANCEROLOGIE DE L'OUEST, +33 2406799000, promotionrc@ico.unicancer.fr

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	13 September 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 September 2023
Global end of trial reached?	Yes
Global end of trial date	13 September 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the concordance for tumor lesion detection using 89Zr-TLX250 PET/CT versus a conventional 18FDG PET/CT scan where comparison will be made on a per lesion analysis basis

Protection of trial subjects:

In order to ensure the protection of the rights, safety and well-being of trial subjects, this clinical trial was performed in compliance with the principles laid down in the declaration of Helsinki, good Clinical Practice and European regulation.

Background therapy: -

Evidence for comparator:

Not applicable

Actual start date of recruitment	01 February 2021
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	3 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 12
Worldwide total number of subjects	12
EEA total number of subjects	12

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)	5
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The first patient signed the informed consent and was included on 21 SEP 2021. The last patient was included on 17 MAY 2023

Pre-assignment

Screening details:

Patient with metastatic Triple Negative Breast Cancer (TNBC). 12 patients have been screened and included in the trial.

Period 1

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

Arms

Arm title	89Zr- Girentuximab (89Zr-TLX250)
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Arm description:

89Zr-TLX250 is administered on day 0. a whole body PET/CT scan is performed on day 5 (+/-2).

Arm type	Experimental
Investigational medicinal product name	89Zr-TLX250
Investigational medicinal product code	
Other name	89Zr- Girentuxima
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Intravenous use

Dosage and administration details:

The mass dose of 89Zr-TLX250 to be used in this study will be 10 mg, labelled with 37 MBq ($\pm 10\%$) 89Zr per dose. Each patient will receive a single slow intravenous (IV) administration over a minimum of 3 minutes on Day 0 (after pre-dose assessments), at the nuclear medicine service of the respective study site. On D5 (± 2) days post administration of 89Zr-TLX250, a whole body PET/CT scan will be acquired from skull to mid-thigh using 6-8 bed positions with 10 minute acquisition time per bed position.

Number of subjects in period 1	89Zr- Girentuximab (89Zr-TLX250)
Started	12
Completed	12

Baseline characteristics

Reporting groups

Reporting group title	Overall trial (overall period)
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Reporting group description: -

Reporting group values	Overall trial (overall period)	Total	
Number of subjects	12	12	
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)	5	5	
From 65-84 years	7	7	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	12	12	
Male	0	0	

End points

End points reporting groups

Reporting group title	89Zr- Girentuximab (89Zr-TLX250)
Reporting group description: 89Zr-TLX250 is administered on day 0. a whole body PET/CT scan is performed on day 5 (+/-2).	

Primary: Number of total lesions

End point title	Number of total lesions ^[1]
End point description: The number of total lesions detected on 89Zr-TLX250 PET/CT versus 18FDG PET/CT is reported to assess the concordance for tumor lesion detection using 89Zr-TLX250 PET/CT and 18FDG PET/CT during the study period.	
End point type	Primary
End point timeframe: 5 days after 89Zr-TLX250 administration	

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 inferential statistical analysis was planned for this endpoint. The results are presented descriptively as a comparison of the number of total lesions detected on 89Zr-TLX250 PET/CT versus 18FDG PET/CT

End point values	89Zr- Girentuximab (89Zr-TLX250)			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: lesions				
89Zr-TLX250 PET/CT	264			
18FDG PET/CT	231			

Statistical analyses

No statistical analyses for this end point

Primary: Number of brain lesions

End point title	Number of brain lesions ^[2]
End point description: Number of brain lesions seen on 89Zr-TLX250 PET/CT and on 18FDG PET/CT will be reported in order to evaluate the sensitivity of 89Zr-TLX250 PET/CT and 18FDG PET/CT. The detection performance of 89Zr-TLX250 PET/CT and 18FDG PET/CT for identifying brain lesions has been compared.	
End point type	Primary
End point timeframe: 5 days after 89Zr-TLX250 administration	

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: No inferential statistical analysis was planned for this endpoint. The results are presented descriptively as a comparison of the number of bone lesions detected on 89Zr-TLX250 PET/CT versus 18FDG PET/CT

End point values	89Zr-Girentuximab (89Zr-TLX250)			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: lesions				
89Zr-TLX250 PET/CT	3			
18FDG PET/CT	1			

Statistical analyses

No statistical analyses for this end point

Primary: Number of breast lesions

End point title	Number of breast lesions ^[3]
End point description:	
Number of breast lesions seen on 89Zr-TLX250 PET/CT and on 18FDG PET/CT will be reported in order to evaluate the sensitivity of 89Zr-TLX250 PET/CT and on 18FDG PET/CT	
End point type	Primary
End point timeframe:	
5 days after 89Zr-TLX250 PET/CT administration	

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: No inferential statistical analysis was planned for this endpoint. The results are presented descriptively as a comparison of the number of lymph nodes lesions detected on 89Zr-TLX250 PET/CT versus 18FDG PET/CT

End point values	89Zr-Girentuximab (89Zr-TLX250)			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: lesions				
89Zr-TLX250 PET/CT	25			
18FDG PET/CT	23			

Statistical analyses

No statistical analyses for this end point

Primary: Number of bone lesions

End point title	Number of bone lesions ^[4]
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End point description:

Number of bone lesions seen on 89Zr-TLX250 PET/CT and on 18FDG PET/CT will be reported in order to evaluate the sensitivity of 89Zr-TLX250 PET/CT and on 18FDG PET/CT

End point type	Primary
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End point timeframe:

5 days after 89Zr-TLX250 PET/CT administration

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: No inferential statistical analysis was planned for this endpoint. The results are presented descriptively as a comparison of the number of lung lesions detected on 89Zr-TLX250 PET/CT versus 18FDG PET/CT

End point values	89Zr-Girentuximab (89Zr-TLX250)			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: lesions				
89Zr-TLX250 PET/CT	102			
18FDG PET/CT	111			

Statistical analyses

No statistical analyses for this end point

Primary: Number of lymph nodes lesions

End point title	Number of lymph nodes lesions ^[5]
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End point description:

Number of lymph nodes lesions seen on 89Zr-TLX250 PET/CT and on 18FDG PET/CT will be reported in order to evaluate the sensitivity of 89Zr-TLX250 PET/CT and on 18FDG PET/CT

End point type	Primary
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End point timeframe:

5 days after 89Zr-TLX250 PET/CT administration

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: No inferential statistical analysis was planned for this endpoint. The results are presented descriptively as a comparison of the number of liver lesions detected on 89Zr-TLX250 PET/CT versus 18FDG PET/CT

End point values	89Zr-Girentuximab (89Zr-TLX250)			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: lesions				
89Zr-TLX250 PET/CT	65			
18FDG PET/CT	74			

Statistical analyses

No statistical analyses for this end point

Primary: Number of lung lesions

End point title	Number of lung lesions ^[6]
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End point description:

Number of lung lesions seen on 89Zr-TLX250 PET/CT and on 18FDG PET/CT will be reported in order to evaluate the sensitivity of 89Zr-TLX250 PET/CT and on 18FDG PET/CT

End point type	Primary
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End point timeframe:

5 days after 89Zr-TLX250 PET/CT administration

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: No inferential statistical analysis was planned for this endpoint. The results are presented descriptively as a comparison of the number of brain lesions detected on 89Zr-TLX250 PET/CT versus 18FDG PET/CT

End point values	89Zr- Girentuximab (89Zr-TLX250)			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: lesions				
89Zr-TLX250 PET/CT	17			
18FDG PET/CT	27			

Statistical analyses

No statistical analyses for this end point

Primary: Number of liver lesions

End point title	Number of liver lesions ^[7]
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End point description:

Number of liver lesions seen on 89Zr-TLX250 PET/CT and on 18FDG PET/CT will be reported in order to evaluate the sensitivity of 89Zr-TLX250 PET/CT and on 18FDG PET/CT

End point type	Primary
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End point timeframe:

5 days after 89Zr-TLX250 PET/CT administration

Notes:

[7] - 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 inferential statistical analysis was planned for this endpoint. The results are presented descriptively as a comparison of the number of breast lesions detected on 89Zr-TLX250 PET/CT versus 18FDG PET/CT

End point values	89Zr-Girentuximab (89Zr-TLX250)			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: lesions				
89Zr-TLX250 PET/CT	12			
18FDG PET/CT	19			

Statistical analyses

No statistical analyses for this end point

Secondary: concordance between 89Zr-TLX250 PET/CT uptake and CAIX histological expression

End point title	concordance between 89Zr-TLX250 PET/CT uptake and CAIX histological expression
End point description:	
Number of patients with a concordance between the 89Zr-TLX250 PET/CT uptake and CAIX histological expression considered as positive or negative	
End point type	Secondary
End point timeframe:	
5 days after 89Zr-TLX250 PET/CT administration	

End point values	89Zr-Girentuximab (89Zr-TLX250)			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: participants				
concordance	7			
No concordance	5			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

30 days after 89Zr-TLX250 PET/CT administration

Adverse event reporting additional description:

All Adverse Events related to 89Zr-TLX250 are reported and assessed using CTCAE v5.0 scale

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	10.0
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Reporting groups

Reporting group title	Safety of 89Zr-TLX250
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Reporting group description:

safety data collected 30 days after 89Zr-TLX250 administration

Serious adverse events	Safety of 89Zr-TLX250		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (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	Safety of 89Zr-TLX250		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 12 (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 adverse events (serious or non-serious) and no deaths were reported during the study period.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 June 2022	Extension of the recruitment period by 18 months and amendment of an inclusion criterion. Transmission of patients safety data.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/41174094>