



Clinical trial results:

Pilot Feasibility Study: Inflammation and presence of M2 macrophages explorations with[18F]-DPA-714 PET/CT in Triple Negative breast cancers

Summary

EudraCT number	2019-001463-75
Trial protocol	FR
Global end of trial date	21 July 2021

Results information

Result version number	v1 (current)
This version publication date	10 July 2026
First version publication date	10 July 2026

Trial information

Trial identification

Sponsor protocol code	ICO-2019-04
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04320030
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	Nadia ALLAM, Project Manager, INSTITUT DE CANCEROLOGIE DE L'OUEST, +33 2 40 67 98 26, nadia.allam@ico.unicancer.fr
Scientific contact	Nadia ALLAM, Project Manager, INSTITUT DE CANCEROLOGIE DE L'OUEST, +33 2 40 67 98 26, nadia.allam@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	21 July 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 July 2021
Global end of trial reached?	Yes
Global end of trial date	21 July 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Study of correlations between tumor immunohistochemical analysis (IHC) and in vivo [18F]-DPA-714 PET/TDM analysis for detection of M2 macrophages infiltrating breast cancer tumor Triple Negative

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:

[18F]DPA-714

Evidence for comparator:

Not applicable

Actual start date of recruitment	02 December 2019
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: 13
Worldwide total number of subjects	13
EEA total number of subjects	13

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	5
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

1st consent signature: 10/06/2020, 1st inclusion: 11/06/2020, LVLP: 21/07/2021

Pre-assignment

Screening details:

Primary Triple Negative Breast Cancer before surgery

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	[18F]DPA-714
Arm description: [18F]DPA-714 PET-CT	
Arm type	Experimental
Investigational medicinal product name	[18F]DPA-714
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for concentrate for solution for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

[18F]DPA-714 is administered at a dose of 3.5 MBq/kg $\pm$ 10%, with a minimum of 150 MBq and a maximum of 400 MBq.

Dynamic PET images are performed in list mode for 30 minutes.

60 min after [18F]DPA-714 injection, precubitus acquisition centred on the thorax + axillary cavities is performed for approximately 15 min.

Number of subjects in period 1	[18F]DPA-714
Started	13
Completed	13

Baseline characteristics

Reporting groups

Reporting group title	Overall trial
Reporting group description: [18F]DPA-714	

Reporting group values	Overall trial	Total	
Number of subjects	13	13	
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)	7	7	
From 65-84 years	5	5	
85 years and over	1	1	
Gender categorical			
Units: Subjects			
Female	13	13	
Male	0	0	

Subject analysis sets

Subject analysis set title	M1/M2 macrophage polarisation
Subject analysis set type	Per protocol

Subject analysis set description:

M1/M2 macrophage polarization has been assessed by tumor immunohistochemistry analysis.

Subject analysis set title	Correlation Between % M2 Using CD163 and SUV Max [18F]DPA-714
Subject analysis set type	Per protocol

Subject analysis set description:

Correlation between % M2 Correlation between M1/M2 macrophages using CD68 and SUV max [18F]DPA-714 has been assessed using a Spearman correlation coefficient.

If p value > 0.05, no significant correlation

Subject analysis set title	Correlation Between M1/M2 Macrophages With CD68 and SUV Max [1
Subject analysis set type	Per protocol

Subject analysis set description:

Correlation between M1/M2 macrophages with CD68 and SUV max [18F]DPA-714 PET/CT using spearman's correlation

Subject analysis set title	Correlation Between TSPO Genotype (HAB, MAB and LAB) and [18F]
Subject analysis set type	Per protocol

Subject analysis set description:

Tumor uptake of [18F]DPA-714 was assessed using dynamic PET/CT time-activity curves (TACs). Uptake patterns were classified relative to the contralateral pectoral muscle (reference tissue) into three

predefined categories: above, equal to, or below muscular background. These categories were compared across TSPO genotypes (HAB = High Affinity Binder, MAB = Mixed Affinity Binder and LAB = Low Affinity Binder) determined from blood samples.

Reporting group values	M1/M2 macrophage polarisation	Correlation Between % M2 Using CD163 and SUV Max [18F]DPA-714	Correlation Between M1/M2 Macrophages With CD68 and SUV Max [1
Number of subjects	13	13	13
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)	7		
From 65-84 years	5		
85 years and over	1		
Gender categorical Units: Subjects			
Female	13		
Male	0		

Reporting group values	Correlation Between TSPO Genotype (HAB, MAB and LAB) and [18F]		
Number of subjects	13		
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Gender categorical Units: Subjects			
Female			
Male			

End points

End points reporting groups

Reporting group title	[18F]DPA-714
Reporting group description: [18F]DPA-714 PET-CT	
Subject analysis set title	M1/M2 macrophage polarisation
Subject analysis set type	Per protocol
Subject analysis set description: M1/M2 macrophage polarization has been assessed by tumor immunohistochemistry analysis.	
Subject analysis set title	Correlation Between % M2 Using CD163 and SUV Max [18F]DPA-714
Subject analysis set type	Per protocol
Subject analysis set description: Correlation between % M2 Correlation between M1/M2 macrophages using CD68 and SUV max [18F]DPA-714 has been assessed using a Spearman correlation coefficient. If p value > 0.05, no significant correlation	
Subject analysis set title	Correlation Between M1/M2 Macrophages With CD68 and SUV Max [1
Subject analysis set type	Per protocol
Subject analysis set description: Correlation between M1/M2 macrophages with CD68 and SUV max [18F]DPA-714 PET/CT using spearman's correlation	
Subject analysis set title	Correlation Between TSPO Genotype (HAB, MAB and LAB) and [18F]
Subject analysis set type	Per protocol
Subject analysis set description: Tumor uptake of [18F]DPA-714 was assessed using dynamic PET/CT time-activity curves (TACs). Uptake patterns were classified relative to the contralateral pectoral muscle (reference tissue) into three predefined categories: above, equal to, or below muscular background. These categories were compared across TSPO genotypes (HAB = High Affinity Binder, MAB = Mixed Affinity Binder and LAB = Low Affinity Binder) determined from blood samples.	

Primary: M1/M2 Macrophage Polarization

End point title	M1/M2 Macrophage Polarization ^[1]
End point description: M1/M2 macrophage polarization has been assessed by tumor immunohistochemistry analysis.	
End point type	Primary
End point timeframe: 2 months	

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: This endpoint is descriptive and no formal statistical comparison is planned due to the single-arm design.

End point values	[18F]DPA-714			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: participants				
Preponderance of M2-polarised macrophages	11			
Non preponderance of M2-polarised macrophages	2			

Statistical analyses

No statistical analyses for this end point

Primary: Correlation Between % M2 Using CD163 and SUV Max [18F]DPA-714 PET/CT

End point title	Correlation Between % M2 Using CD163 and SUV Max [18F]DPA-714 PET/CT ^[2]
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End point description:

Correlation between % M2 Correlation between M1/M2 macrophages using CD68 and SUV max [18F]DPA-714 has been assessed using a Spearman correlation coefficient.
If p value > 0.05, no significant correlation

End point type	Primary
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End point timeframe:

2 months

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: This endpoint is descriptive and no formal statistical comparison is planned due to the single-arm design.

End point values	[18F]DPA-714	Correlation Between % M2 Using CD163 and SUV Max [18F]DPA-714		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	13	13		
Units: Spearman's rho				
number (not applicable)				
Spearman's rho	-0.45	-0.45		
p value	0.12	0.12		

Statistical analyses

No statistical analyses for this end point

Primary: Correlation Between M1/M2 Macrophages With CD68 and SUV Max [18F]DPA-714 PET/CT

End point title	Correlation Between M1/M2 Macrophages With CD68 and SUV Max [18F]DPA-714 PET/CT ^[3]
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End point description:

Correlation between M1/M2 macrophages with CD68 and SUV max [18F]DPA-714 PET/CT using spearman's correlation

End point type	Primary
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End point timeframe:

2 months

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: This endpoint is descriptive and no formal statistical comparison is planned due to the single-arm design.

End point values	[18F]DPA-714			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: Spearman's rho				
number (not applicable)				
Spearman's rho	-0.30			
p value	0.31			

Statistical analyses

No statistical analyses for this end point

Secondary: Correlation Between TSPO Genotype (HAB, MAB and LAB) and [18F]DPA-714 PET/CT Tumor Uptake

End point title	Correlation Between TSPO Genotype (HAB, MAB and LAB) and [18F]DPA-714 PET/CT Tumor Uptake
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End point description:

Tumor uptake of [18F]DPA-714 was assessed using dynamic PET/CT time-activity curves (TACs). Uptake patterns were classified relative to the contralateral pectoral muscle (reference tissue) into three predefined categories: above, equal to, or below muscular background. These categories were compared across TSPO genotypes (HAB, MAB, LAB) determined from blood samples.

End point type	Secondary
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End point timeframe:

2 months

End point values	[18F]DPA-714			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: participants				
HAB - Above muscular background	2			
HAB - Equal to muscular background	3			
HAB - Below muscular background	0			
MAB - Above muscular background	2			
MAB - Equal to muscular background	3			
MAB - Below muscular background	1			
LAB - Above muscular background	0			
LAB - Equal to muscular background	1			
LAB - Below muscular background	1			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Adverse Events reporting: from consent signature to 28 days after [18F]DPA-714 administration

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	3
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Reporting groups

Reporting group title	[18F]DPA-714
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Reporting group description: -

Serious adverse events	[18F]DPA-714		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 13 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	[18F]DPA-714		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 13 (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
01 July 2020	Clarify the [18F]DPA-714 PET/CT procedure, the MRI procedure and an exclusion criterion. Modification of SAEs declaration procedure. Modification of informed consent: add signature of consent for genotyping of the TSP0 translocator protein in blood
21 September 2020	Declaration of a new [18F]DPA-714 production center

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.

No

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/38913962>