Clinical trial results:
The Role Of The New Promising Oncological Pet/Ct Tracer [68Ga] Ga-Fapi For Staging Lung Cancer: A Preliminary Study

Summary

EudraCT number	2021-006570-23
Trial protocol	IT
Global end of trial date	30 November 2024

Results information

Result version number	v1 (current)
This version publication date	16 December 2025
First version publication date	16 December 2025

Trial information

Trial identification

Sponsor protocol code	FAPI-POLMONE-2021

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	IRCCS Azienda Ospedaliero-Universitaria di Bologna
Sponsor organisation address	Via Albertoni 15, Bologna, Italy, 40138
Public contact	Dott.ssa Lucia Zanoni, U.O. Medicina Nucleare, IRCCS AOU di Bologna, Policlinico di S.Orsola, Bologna, Italy, zanonilucia84@gmail.com
Scientific contact	Dott.ssa Lucia Zanoni, U.O. Medicina Nucleare, IRCCS AOU di Bologna, Policlinico di S.Orsola, Bologna, Italy, zanonilucia84@gmail.com

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	08 May 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 November 2024
Global end of trial reached?	Yes
Global end of trial date	30 November 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The study aims to evaluate the diagnostic performance of PET / CT with 68Ga-FAPI, in patients with staging lung cancer, in the identification of disease locations by comparing the (overall) evaluation of the 68Ga-FAPI outcome PET / CT with histological data

Protection of trial subjects:

Yes (insurance)

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 May 2022
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy, Scientific research
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Italy: 64
Worldwide total number of subjects	64
EEA total number of subjects	64

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)	14
From 65 to 84 years	48
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

Recruitment dates: from 26May2022 to 30November2023
Recruitment: Nuclear Medicine, AOU di Bologna, Bologna, Italy

Pre-assignment

Screening details:

63 subjects underwent the experimental 68Ga-FAPI-46 PET/CT out of the 64 subjects enrolled: 1/64 subjects withdrawed consent before IMP (68Ga-FAPI-46) administration and was excluded from analyses (1 screening failure)

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	Overall Trial Single arm

Arm description:

single arm study

Each patient underwent FAPI-PET/CT in addition to its conventional staging flow-chart. No changes in pts management, nor delay in standard diagnostic and
therapeutic flow-chart, derived from FAPI-PET/CT results. Treatment plan decided by the referring clinicians on the basis of standard clinical and imaging staging flow-chart.

Arm type	Experimental
Investigational medicinal product name	68Ga-FAPI-46
Investigational medicinal product code	[68Ga-FAPI-46]
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

dosage range 150 to 250 MBq

Number of subjects in period 1[1]	Overall Trial Single arm
Started	63
Completed	63

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 63 subjects underwent the experimental 68Ga-FAPI-46 PET/CT out of the overall 64 subjects enrolled: 1/64 subject withdrawed consent before IMP (68Ga-FAPI-46) administration and was excluded from analyses (1 screening failure)

Baseline characteristics

Reporting groups

Reporting group title	overall Trial

Reporting group description: -

Reporting group values	overall Trial	Total	
Number of subjects	63	63	
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)	14	14	
From 65-84 years	47	47	
85 years and over	2	2	
Age continuous Units: years			
arithmetic mean	71		
full range (min-max)	45 to 87	-	
Gender categorical Units: Subjects			
Female	22	22	
Male	41	41	

Subject analysis sets

Subject analysis set title	Surgical
Subject analysis set type	Full analysis

Subject analysis set description:

Pts referred (according to standard practice) to radical surgery, undergoing standard pathology evaluation and routinely
monitored (Thoracic surgery Unit) for 1 year

Subject analysis set title	Non surgical
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Patients excluded from surgery, on the basis of standard clinical and imaging staging flow-chart (non-surgical patients): 68Ga-FAPI PET / CT positivity rate and agreement with conventional staging calculated.

Reporting group values	Surgical	Non surgical	
Number of subjects	50	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			
Age continuous Units: years			
arithmetic mean	72	67	
full range (min-max)	45 to 87	52 to 83	
Gender categorical Units: Subjects			
Female	17	5	
Male	33	8	

End points

End points reporting groups

Reporting group title	Overall Trial Single arm

Reporting group description:

single arm study

Each patient underwent FAPI-PET/CT in addition to its conventional staging flow-chart. No changes in pts management, nor delay in standard diagnostic and
therapeutic flow-chart, derived from FAPI-PET/CT results. Treatment plan decided by the referring clinicians on the basis of standard clinical and imaging staging flow-chart.

Subject analysis set title	Surgical
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Subject analysis set title	Non surgical
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Patients excluded from surgery, on the basis of standard clinical and imaging staging flow-chart (non-surgical patients): 68Ga-FAPI PET / CT positivity rate and agreement with conventional staging calculated.

Primary: Endpoint 1a (primary): PET/CT diagnostic performance of FAPI, patient-based, for T (n=50)

End point title	Endpoint 1a (primary): PET/CT diagnostic performance of FAPI, patient-based, for T (n=50)[1]

End point description:

Time required for subsequent histological examination (Patients underwent surgery mostly within 2 months from the experimental imaging,
with a median of 40.5 days).

In pts who underwent surgical treatment, the pathology examination routinely processed of the lung was used as standard of truth to define 68Ga-FAPI PET/CT scans results as true positive (TP), true negative (TN), false positive (FP) or false negative (FN).
Sensitivity, specificity, accuracy, positive and negative predictive value (PPV and NPV) were calculated, with relative 95% confidence intervals (95% CI), on a per patient analysis, to evaluate the performance of PET / CT with 68Ga-FAPI for malignant lung lesion (T).

FAPI PET/CT results for T:
42 TP
2 FN
2 FP
4 TN

End point type	Primary

End point timeframe:

36 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: According to the trial protocol: sensitivity, specificity, accuracy, PPV and NPV were calculated, with relative 95% confidence intervals (95% CI), on a per patient analysis, to evaluate the performance of PET / CT with 68Ga-FAPI for T.

End point values	Surgical			
Subject group type	Subject analysis set			
Number of subjects analysed	50[2]			
Units: number of sens, spec, ppv, npv, acc				
number (confidence interval 95%)				
sensitivity	0.955 (0.893 to 1.016)			
specificity	0.667 (0.289 to 1.044)			
ppv	0.955 (0.893 to 1.016)			
npv	0.667 (0.289 to 1.044)			
accuracy	0.920 (0.845 to 0.995)			

Notes:

[2] - comparison of overall FAPI result with surgical histopathology of lung (T)

Statistical analyses

No statistical analyses for this end point

Primary: Endpoint 1b (primary): PET/CT diagnostic performance of FAPI, patient-based, for N (n=46)

End point title	Endpoint 1b (primary): PET/CT diagnostic performance of FAPI, patient-based, for N (n=46)[3]

End point description:

Time required for subsequent histological examination (Patients underwent surgery mostly within 2 months from the experimental imaging, with a median of 40.5 days).

In pts who underwent surgical treatment, the pathology examination of N stations routinely processed was used as standard of truth to
define 68Ga-FAPI PET/CT scans results as true positive (TP), true negative (TN), false positive (FP) or false negative (FN).
Sensitivity, specificity, accuracy, PPV and NPV was calculated, with relative 95% confidence intervals (95% CI, on a per patient analysis, to evaluate the performance of PET / CT with 68Ga-FAPI for lymph-node stations (N).

FAPI PET/CT results for N:
6 TP
6 FN
4 FP
30 TN

End point type	Primary

End point timeframe:

36 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: According to the trial protocol: sensitivity, specificity, accuracy, PPV and NPV were calculated, with relative 95% confidence intervals (95% CI), on a per patient analysis, to evaluate the performance of PET / CT with 68Ga-FAPI for N.

End point values	Surgical			
Subject group type	Subject analysis set			
Number of subjects analysed	46[4]			
Units: sens, spec, ppv, npv, acc				
number (confidence interval 95%)				
sensitivity	0.500 (0.217 to 0.783)			
specificity	0.882 (0.774 to 0.991)			
ppv	0.600 (0.296 to 0.904)			
npv	0.833 (0.712 to 0.955)			
accuracy	0.783 (0.663 to 0.902)			

Notes:

[4] - Among the 50 patients of the surgical cohort, 46 were subjected to lymphadenectomy

Statistical analyses

No statistical analyses for this end point

Secondary: Endpoint 2a: PET/CT diagnostic performance of FAPI, region-based, for T (n=59)

End point title	Endpoint 2a: PET/CT diagnostic performance of FAPI, region-based, for T (n=59)

End point description:

Time required for subsequent histological examination (Patients underwent surgery mostly within 2 months from the experimental imaging,
with a median of 40.5 days).

Sensitivity, specificity, accuracy, PPV and NPV were calculated, with relative 95% confidence intervals (95% CI), on a per region analysis, to evaluate the performance of PET / CT with 68Ga-FAPI for T.
In patients referred for radical surgery, the results of PET/CT were validated by the histopathological examination, performed according to the normal care pathway, of the surgical samples of lung lesioins (T).

FAPI PET/CT results for T regions (n=59):
TP 45
FN 8
FP 2
TN 4

End point type	Secondary

End point timeframe:

36 months

End point values	Surgical			
Subject group type	Subject analysis set			
Number of subjects analysed	50[5]			
Units: sens, spec, ppv, npv, acc				
number (confidence interval 95%)				
sensitivity	0.849 (0.753 to 0.945)			

specificity	0.667 (0.289 to 1.044)			
ppv	0.957 (0.900 to 1.015)			
npv	0.333 (0.067 to 0.600)			
accuracy	0.831 (0.735 to 0.926)			

Notes:

[5] - Among the 50 patients of the surgical cohort, 59 lung lesions (T) were examined

Statistical analyses

No statistical analyses for this end point

Secondary: Endpoint 2b: PET/CT diagnostic performance of FAPI, region-based, for N (n=217)

End point title	Endpoint 2b: PET/CT diagnostic performance of FAPI, region-based, for N (n=217)

End point description:

Time required for subsequent histological examination (Patients underwent surgery mostly within 2 months from the experimental imaging,
with a median of 40.5 days).

Sensitivity, specificity, accuracy, PPV and NPV were calculated, with relative 95% confidence intervals (95% CI), on a N region based analysis, to evaluate the performance of PET / CT with 68Ga-FAPI for N. In patients referred for radical surgery, the results of PET/CT (N) were validated by the surgical histopathological examination, performed according to the normal care pathway, of the resecteted lymphnodes.

FAPI PET/CT results for N region:
TP 8
FN 7
FP 7
TN 195

End point type	Secondary

End point timeframe:

36 months

End point values	Surgical			
Subject group type	Subject analysis set			
Number of subjects analysed	46[6]			
Units: sens, spec, ppv, npv, acc				
number (confidence interval 95%)				
sensitivity	0.533 (0.281 to 0.786)			
specificity	0.965 (0.940 to 0.991)			
ppv	0.533 (0.281 to 0.786)			
npv	0.965 (0.940 to 0.991)			
accuracy	0.935 (0.903 to 0.968)			

Notes:

[6] - 46 out of 50 surgical patients addressed to nodal dissection: overall, 217 N-stations examined

Statistical analyses

No statistical analyses for this end point

Secondary: Endpoint 3: concordance of 68Ga-FAPI PET/CT with final conventional staging in pts excluded from radical surgery

End point title	Endpoint 3: concordance of 68Ga-FAPI PET/CT with final conventional staging in pts excluded from radical surgery

End point description:

In pts excluded from surgery, positivity rate was calculated and concordance with conventional Tstaging was assessed

End point type	Secondary

End point timeframe:

36 months

End point values	Non surgical			
Subject group type	Subject analysis set			
Number of subjects analysed	13[7]			
Units: %				
% positivity rate FAPI for T	77			
% positivity rate FAPI for N	50			
% agreement T between FAPI and biopsy	60			
% agreement N between FAPI and biopsy	95			
% agreement T standard FDG PET with biopsy	60			
% agreement N standard FDG PET with biopsy	75			

Notes:

[7] - 13 patients not adressed to surgery: 13 T and 20 N regions examined.

Statistical analyses

No statistical analyses for this end point

Secondary: Endpoint 4a: FAPI PET/CT diagnostic performance using semiquantitative PET parameters, region-based, for T

End point title	Endpoint 4a: FAPI PET/CT diagnostic performance using semiquantitative PET parameters, region-based, for T

End point description:

The performance of continuous semiquatitative PET variables (for example SUVmax and target to background ratios-TBRs) were evaluated in relation to the result of the histological examination of T,

when available.

MBP=mediastinal blood pool
AUC= area under the curve

End point type	Secondary

End point timeframe:

36 months

End point values	Surgical			
Subject group type	Subject analysis set			
Number of subjects analysed	50[8]			
Units: AUC				
number (confidence interval 95%)				
AUC SUVmax-T (Tmax)	0.61 (0.3342 to 0.889)			
AUC TBR-L (Tmax/Liver mean)	0.64 (0.3347 to 0.9389)			
AUC TBR-MBP (Tmax/MBP mean)	0.65 (0.3573 to 0.9445)			
AUC TBR-P (Tmax/Lung mean)	0.63 (0.3226 to 0.9415)			

Notes:

[8] - Among the 50 patients of the surgical cohort, 59 lung lesions (T) were examined

Statistical analyses

No statistical analyses for this end point

Secondary: Endpoint 4b: FAPI PET/CT diagnostic performance using semiquantitative PET parameters, region-based, for N

End point title	Endpoint 4b: FAPI PET/CT diagnostic performance using semiquantitative PET parameters, region-based, for N

End point description:

The performance of continuous semiquatitative PET variables (for example SUVmax and TBR) were evaluated in relation to the result of the histological examination, when available.

End point type	Secondary

End point timeframe:

36 months

End point values	Surgical			
Subject group type	Subject analysis set			
Number of subjects analysed	46[9]			
Units: AUC				
number (confidence interval 95%)				
AUC SUVmax-N (Nmax)	0.79 (0.6477 to 0.9099)			

AUC TBR-L (Nmax/Liver mean)	0.78 (0.6538 to 0.9099)			
AUC TBR-MBP (Nmax/MBP mean)	0.78 (0.6477 to 0.9094)			
AUC TBR-P (Nmax/Lung mean)	0.78 (0.6465 to 0.9071)			

Notes:

[9] - 46 out of 50 surgical patients addressed to nodal dissection: overall, 217 N-stations examined.

Statistical analyses

No statistical analyses for this end point

Secondary: Endpoint 5: comparison hypothetical treatment plan derived from 68Ga-FAPI with the conventional treatment already performed

End point title	Endpoint 5: comparison hypothetical treatment plan derived from 68Ga-FAPI with the conventional treatment already performed

End point description:

At the end of the standard management of pts included in the study, a hypothetical treatment plan using the FAPI-PET/CT results was defined. The conventional and already performed treatment plan (derived from the conventional staging flow-chart) and the hypothetical one (derived from FAPI) were compared to assess a only theoretical potential clinical impact of the new tracer in the next future.
final TNMstaging (stageI-IV) assessed by AJCC8thEdition.

End point type	Secondary

End point timeframe:

End of Trial

End point values	Surgical			
Subject group type	Subject analysis set			
Number of subjects analysed	50[10]			
Units: agreement %				
% agreement fapi-histology TNM	48			
% agreement fdg-histology TNM	43			
% FAPI-FDG discordant cases	30			
% FDG-derived correct surgical management	69			
% FAPI-derived correct surgical management	87			

Notes:

[10] - surgical cohort (TNM final staging determined by surgical histopathology as standard of truth)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

1 month from FAPI PET/CT (as per protocol)

Adverse event reporting additional description:

no

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.1

Reporting groups

Reporting group title	overall trial

Reporting group description: -

Serious adverse events	overall trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 63 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 63 (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: There are not recorded adverse events for the timeframe

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