EU Clinical Trials Register

Clinical trial results: *Full title of Trial**

Summary

EudraCT number*	2015-000679-28
Trial protocol	IT
Global end of trial date*	9/04/2018

Trial information

Trial identification	
Sponsor protocol code*	FAZA-gliomi
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	if available
WHO universal trial number (UTN)	-

Notes:

Sponsors details*	
Sponsor organisation name	IRCCS Ospedale San Raffaele
Sponsor organisation address	Via Olgettina, 60, Milano, Italy, 20132
Public contact	
Scientific contact	Maria Picchio picchio.maria@hsr.it

Notes:

Paediatric regulatory details*	
Is trial part of an agreed paediatric investigation plan (PIP)	Yes or **No**
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes or No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes or No

Results analysis stage	
Analysis stage*	Interim or **Final**
Date of interim/final analysis*	9/04/2018 (data di chiusura studio)
Is this the analysis of the primary completion data?*	Yes or No
Global end of trial reached?*	Yes or No
Global end of trial date*	9/04/2018 (data di chiusura studio)
Was the trial ended prematurely?	Yes or **No**

General information about the trial

Main objective of the trial*: *Enter a description for the mail objective(s) of the trial*
Value of 18F-FAZA PET/CT in high-grade glioma

Actual start date of recruitment*	8/04/2016
Long term follow-up planned*	Yes or No
If Yes, rationale:	Safety Efficacy Ethical reason Regulatory reason Scientific research
Duration	Months - Years
Independent data monitoring committee (IDMC) involvement?*	Yes or No
Protection of trial subjects*:	
Background therapy:	
Evidence for comparator:	

Population of trial subjects

Subjects enrolled per country

Country:	Italy
Planned number of subjects	20
Actual Number of subjects enrolled*	20
Worldwide total number of subjects	20
EEA total number of subjects	20

Subjects enrolled per age group

In utero*	0
Preterm newborn - gestational age < 37wks*	0
Newborns (0-27 days)*	0
Infants and toddlers (28 days-23months)*	0
Children (2-11 years)*	0
Adolescents (12-17 years)*	0
Adults (18-64 years)*	12
From 65 to 84 years*	8
85 years and over*	0

Subject disposition

Recruitment details: *Enter key information relevant to the recruitment process for the trial (eg gates of recruitment period and territories)*

Patients with brain MRI suggestive for High Grade Glioma

Pre-assignment - *Screening details*: *Enter relevant information related to screening (eg screening criteria, significant events and approaches)*

Period 1	
Period title*	*Enter a title describing the stage of the trial. If the only one period is defined, the default title should be "Overall Trial"* ***Overall trial***
Is this the baseline period?	Yes or No
Allocation method*	Randomised - controlled Non-randomised - controlled **Not applicable**
Blinding used*	Double blind Single blind **Not blinded**

Arms	
Arm title*	*Enter a title to identify the arm - Add arm and IMP if applicable* **Not applicable**
Arm description:	
Arm type*	Experimental Active comparator Placebo No intervention Other
Investigational medicinal product name*	**18F-FAZA**
Investigational medicinal product code	
Other name	
Pharmaceutical forms*	**^{18}F-labeled fluoroazomycinarabinoside**
Routes of administration*	**Intravenous bolus**
Dosage and administration details*	**Approximately 370 MBq**

Number of subjects in period	Arm Title (overall population)	Arm Title *(repeat for each arms if applicable)*
Started*	20	
Completed*	18	
Subject non-completion reason (if applicable)	2	
AE, non fatal		
AE, fatal		
Consent withdrawn by subject		
Lack of efficacy		
Lost to follow up		
Physician decision		
Pregnancy		
Protocol Deviation		
Other	FAZA PET study not performed after enrolment	

Baseline characteristics

Reporting groups* Overall cohort	
Reporting group title*	Overall cohort
Number of subjects at the baseline*	20

Reporting group description: *You can report per arm in the baseline period or for the overall baseline period*

Subject analysis sets

Add a subject analysis set if you wish to report on groups different from the reporting group defined above (repeat if applicable)

Subject analysis set title*	*Overall cohort*
Subject analysis set type*	Full Analysis Intention to treat Per protocol Safety analysis Sub-group analysis
Subject analysis set description*	*Overall cohort* *Enter a clear description which defines this set of subjects*
Number of subjects in subjects analysis set*	*17*

Age characteristics*

Complete either the age categorical, age continuous or complete both these characteristics in order to collect values for the reporting groups and optionally the subject analysis sets.

	Characteristic title*	Units*	Age categories*
Age categorical			

	Characteristic title*	Units*	Central tendency*	Dispersion type*
Age continuous	Overall cohort	Years Months Weeks Days	Arithmetic Mean Median least square mean geometric mean log mean	full range (min-max) standard deviation inter quartile range

Gender characteristics*

	Characteristic title*	Units*	Gender categories*
Gender categorical	5 12		Female Male

Study specific characteristics

	Characteristic title*	Units *	Categories*	Number of subject for each categories
Study specific categorical				
Study specific categorical				
Study specific categorical				

Study specific categorical				
Study specific categorical				

End points

Add subject analysis set if you wish to report on groups different form reporting groups defined above

Subject analysis set title*	
Subject analysis set type*	Full Analysis Intention to treat Per protocol Safety analysis Sub-group analysis
Subject analysis set description*	
Number of subject in subject analysis set *	

End points definitions

End point title*	Value of 18F-FAZA PET/CT in high-grade glioma	
		Values
Countable or measurable?*	*Select countable when the end point represents data that contains distinct values.* *NA*	-
If countable, Countable units*:	*NA*	
If measurable, Measurable units*	*NA*	
Measure type*:	Number Arithmetic Mean Median least square mean geometric mean log mean	
Precision/dyspersion type*	*NA*	

End point type*	Primary Secondary Other pre-specified Post Hoc

End point timeframe*: all study duration

Use categories only if the data for the end point can be categorized

Category title

Specify the groups of subjects applicable to this end point

Reporting groups*			
Period			
Arms			
subject analysis sets			

Adverse events

Adverse events information

Timeframe for reporting adverse events*: *Enter the time point(s) or time period for AE assessment*

First patient first visit: 08/04/2016
Last recruitment date: 12/10/2017
Study closure: 09/04/2018

Adverse event reporting additional description: *Enter information about the AE collection and provide details about the method of assessment and monitoring*

No adverse events related to the experimentation occurred during the study period

Assessment type*	Systematic or Non Systematic
Frequency threshold for reporting non-serious adverse events*	*Enter the frequency of non SAE that are reported in the results database for all arms or reporting groups*

Dictionary used

Dictionary name*	MedDRA or CTCAE
Dictionary version*	

Adverse events reporting group definition

Use arms from baseline period as reporting groups
OR

Reporting group title*: *Overall cohort*

For this reporting group, provide the following totals:

Subject exposed*	18
Subjects affected by non -SAE*	0
Total number of deaths (all causes)*	11 (not related to the trial)
Total number of deaths resulting from adverse event*	0

Serious adverse event details and values

System organ class*:

Event term*:

Values for serious adverse event per reporting group *

Reporting groups	Subjects affected number	Subjects exposed number	Occurrences all number	Occurrences causally related to treatment number	Fatalities number	Fatalities causally related to treatment number

Non - Serious adverse event details and values

System organ class*:

Event term*:

Values for non-serious adverse event per reporting group*

Threshold for non-serious adverse event reporting is:

Reporting groups	Subjects affected number	Subjects exposed number	Occurrences all number

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol*? **Yes** or No

Date	Amendment
8/09/2016	The protocol has been amended in order to include patients with high-grade glioma both candidate to stereotactic biopsy and surgical intervention.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial*? Yes or **No**

If Yes, Interruption date

Interruption descrption

Limitations and caveats

None reported

Online references

Enter PubMed identifier (PMID)

PMID: 35911979
Bailo M, Pecco N, Callea M, Scifo P, Gagliardi F, Presotto L, Bettinardi V, Fallanca F, Mapelli P, Gianolli L, Doglioni C, Anzalone N, Picchio M, Mortini P, Falini A, Castellano A. Decoding the heterogeneity of malignant gliomas by positron emission tomography and magnetic resonance imaging for spatial habitat analysis of hypoxia, perfusion, and diffusion imaging: a preliminary study. Frontiers in Neuroscience. July 2022.

PMID: 33741855
Mapelli P, Callea M, Fallanca F, Castellano A, Bailo M, Scifo P, Bettinardi V, Conte GM, Monterisi C, Rancoita PMV, Incerti E, Vuozzo M, Gianolli L, Terreni M, Anzalone N, Picchio M. 18F-FAZA PET/CT in pretreatment assessment of hypoxic status in high-grade glioma: correlation with hypoxia immunohistochemical biomarkers. Nucl Med Commun. 2021

PMID: 32332306
Mapelli P, Fallanca F, Scifo P, Barbera M, Castellano A, Bettinardi V, Incerti E, Gianolli L, Anzalone N, Picchio M. Hypoxia and Amino Acid Imaging of High-Grade Glioma: 18F-FAZA PET/CT and 11C-Methionine PET/MRI. Clin Nucl Med.

PMID: 32079461
Mapelli P and Picchio M. 18F-FAZA PET imaging in tumour hypoxia: a focus on high-grade glioma. The International Journal of Biological Markers. Int J Biol Markers.

PMID: 29035992
Mapelli P, Zerbetto F, Incerti E, Conte GM, Bettinardi V, Fallanca F, Anzalone N, Di Muzio N, Gianolli L, Picchio M.18F-FAZA PET/CT hypoxia imaging of high-grade glioma before and after radiotherapy. Clin Nucl Med

Mapelli P, Incerti E, Bettinardi V, Conte GM, Fallanca F, Bailo M, Vuozzo M, Callea M, Gianolli L, Picchio M. Hypoxia 18F-FAZA PET/CT imaging in lung cancer and high-grade glioma: open issues in clinical application. Clin Transl Imaging (2017) 5:389–397. DOI 10.1007/s40336-017-0240-0.

Quartuccio N, Laudicella R, Mapelli P, Guglielmo P, Pizzuto DA, Boero M, Arnone G, Picchio M. Hypoxia PET imaging beyond 18F-FMISO in patients with high-grade glioma: 18F-FAZA and other hypoxia radiotracers. Clinical and Translational Imaging (2020) 8:11–20; ISSN: 2281-5872 , 2281-7565; DOI: 10.1007/s40336-020-00358-0