Clinical trial results:
Prognostic value of 18F-FAZA PET/CT in high grade glioma: comparison with MRI and correlation with hypoxia biomarkers.

Summary

EudraCT number	2015-000679-28
Trial protocol	IT
Global end of trial date	09 April 2018

Results information

Result version number	v1 (current)
This version publication date	19 October 2022
First version publication date	19 October 2022
Summary attachment (see zip file)	Summary results FAZA-gliomi_ (EUCTR Clinical trials results_PM_7 sett clean.pdf) End of study communication (COMUNICAZIONE FINE STUDIO AL CE_9apr2018.pdf) DSUR (DSUR_SafetyReport_3ott2019.pdf) Article_Nuclear Medicine Communication_28 January 2021_M.Picchio (MAPELLI_ 18F_FAZA_PET_CT_in_pretreatment_assessment_of.pdf) Mapelli 2020 CNM_Hypoxia_and_Amino_Acid_Imaging_of_High_Grade.39 (Mapelli 2020 CNM_Hypoxia_and_Amino_Acid_Imaging_of_High_Grade.39 (2).pdf) Mapelli2017_FAZA_RT_ClinNuclMed (Mapelli2017_FAZA_RT_ClinNuclMed.pdf) Mapelli2017_FAZA_RT_ClinNuclMed (Mapelli2017_Pictorial review CATI.PDF) Mapelli2020_faza_focus on HGG_IJBM (Mapelli2020_faza_focus on HGG_IJBM.PDF) MAPELLI2021_ 18F_FAZA_PET_CT_in_pretreatment_assessment_of (MAPELLI2021_ 18F_FAZA_PET_CT_in_pretreatment_assessment_of.pdf) Quartuccio2020_CATI2020_Hypoxia (Quartuccio2020_CATI2020_Hypoxia.pdf)

Trial information

Trial identification

Sponsor protocol code	FAZA-gliomi

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	IRCCS Ospedale San Raffaele
Sponsor organisation address	Via Olgettina n.60, Milan, Italy, 20132
Public contact	MEDICINA NUCLEARE, IRCCS OSPEDALE SAN RAFFAELE, 0039 02-26436117, picchio.maria@hsr.it
Scientific contact	MEDICINA NUCLEARE, IRCCS OSPEDALE SAN RAFFAELE, 0039 02-26436117, picchio.maria@hsr.it

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	09 April 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 April 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To define the role of PET/CT with 18F-FAZA as a guide to biopsy, to predict patient outcomes, to define the correlation between spatial pseudoprogressione disease / radiation necrosis and hypoxia and to plan radiotherapy treatment in patients with high-grade gliomas.

Protection of trial subjects:

N.A.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 April 2016
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	Italy: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	12
From 65 to 84 years	8
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients with brain MRI suggestive for High Grade Glioma

Pre-assignment

Screening details:

In this prospective clinical study, 20 patients with brain MRI suggestive for HGG have been enrolled from April 2016 to October 2017 at IRCCS OSR. The study population consisted of 13 male and 5 female patients, with a mean age of 66years (range 41–81).

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	Arm 1
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	18F-labeled fluoroazomycinarabinoside
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion
Dosage and administration details: 370 MBq megabecquerel(s) die	
Investigational medicinal product name	18F-labeled fluoroazomycinarabinoside
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Infusion
Dosage and administration details: 370 MBq megabecquerel(s) die	

Number of subjects in period 1[1]	Arm 1
Started	18
Completed	18

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: All recruited patients underwent 18F-FAZA PET/CT before starting treatment, with the exception
of two patients dropped out because of technical issues regarding radiotracer synthesis.

Baseline characteristics

End points

End points reporting groups

Reporting group title	Arm 1

Reporting group description: -

Primary: Value of 18F-FAZA PET/CT in high-grade glioma

End point title	Value of 18F-FAZA PET/CT in high-grade glioma[1]

End point description:

End point type	Primary

End point timeframe:

All study duration

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: Correlations between all PET-derived parameters and anatomopathological features (CA-IX, GLUT-1, average number of capillaries, anti-CD31 antibody and Ki-67) were evaluated by using the nonparametric Spearman's correlation coefficient. For patients with multiple lesions, only PET data of the main lesion were used for computing the correlations. The correlation analysis was performed separately for the two subgroups (surgical and bioptic).

End point values	Arm 1			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: 1				
number (not applicable)	18			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

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

Adverse event reporting additional description:

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

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

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: In this study there are not non serious adverse event (SAE). See DSUR in attach

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 September 2016	The protocol has been amended in ordet 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? No

Limitations and caveats

None reported