Clinical trial results:
Efficacia diagnostica della metodica 18F-DOPA-PET/TC nello studio del Neuroblastoma: confronto con scintigrafia 123I-MIBG.

Summary

EudraCT number	2010-018456-27
Trial protocol	IT
Global end of trial date	20 February 2011

Results information

Result version number	v1 (current)
This version publication date	02 August 2024
First version publication date	02 August 2024
Summary attachment (see zip file)	Comparison of 18F-dopa PET/CTand 123I-MIBG scintigraphy in stage 3 and 4 neuroblastoma: a pilot study (s00259-011-1938-2(2).pdf)

Trial information

Trial identification

Sponsor protocol code	01/2010

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	E.O. Ospedali Galliera
Sponsor organisation address	Mura delle Cappuccine 14, Genoa, Italy, 16128
Public contact	S.S. Gestione attività di ricerca e Grant Office, E.O. Ospedali Galliera , S.S. Gestione attività di ricerca e Grant Office, E.O. Ospedali Galliera , 0039 0105634235, ucs@galliera.it
Scientific contact	S.S. Gestione attività di ricerca e Grant Office, E.O. Ospedali Galliera , S.S. Gestione attività di ricerca e Grant Office, E.O. Ospedali Galliera , 0039 0105634235, ucs@galliera.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	20 February 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 February 2011
Global end of trial reached?	Yes
Global end of trial date	20 February 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

verify the diagnostic efficacy of 18F-DOPA PET/CT compared to traditional imaging methods in the restaging of patients affected by Neuroblastoma

Protection of trial subjects:

At least 4 months of clinical and imaging follow-up data were available for all patients

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2010
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: 19
Worldwide total number of subjects	19
EEA total number of subjects	19

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)	1
Children (2-11 years)	16
Adolescents (12-17 years)	0
Adults (18-64 years)	2
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Neuroblastoma (NB) patients

Pre-assignment

Screening details:

- age>12 months
-patients already treated for NB stage IY with confirmed or suspected disease recovery upon clinical, laboratory and conventional imaging evaluation
-multi-relapsed patients with ascertained or suspected disease recurrence upon clinical, laboratory and conventional imaging evaluation
- Written informed consent

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	Neuroblastoma patients

Arm description:

Neuroblastoma patients who uderwent 18F-DOPA PET/CT

Arm type	Experimental
Investigational medicinal product name	6-[18F]fluoro-L-dopa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Intramuscular and intravenous use

Dosage and administration details:

(4 MBq/Kg) never < 80 MBq

Number of subjects in period 1	Neuroblastoma patients
Started	19
Completed	19

Baseline characteristics

Reporting groups

Reporting group title	overall trial (overall period)

Reporting group description: -

Reporting group values	overall trial (overall period)	Total	
Number of subjects	19	19	
Age categorical Units: Subjects			
Infants and toddlers (28 days-23 months)	1	1	
Adults (18-64 years)	2	2	
children (2 - 11 years)	16	16	
Gender categorical Units: Subjects			
Female	4	4	
Male	15	15	

Subject analysis sets

Subject analysis set title	diagnostic accuracy
Subject analysis set type	Full analysis

Subject analysis set description:
diagnostic accuracy

Reporting group values	diagnostic accuracy		
Number of subjects	19		
Age categorical Units: Subjects			
Infants and toddlers (28 days-23 months)			
Adults (18-64 years)			
children (2 - 11 years)			
Gender categorical Units: Subjects			
Female	15		
Male	4		

End points

End points reporting groups

Reporting group title	Neuroblastoma patients
Reporting group description: Neuroblastoma patients who uderwent 18F-DOPA PET/CT	
Subject analysis set title	diagnostic accuracy
Subject analysis set type	Full analysis
Subject analysis set description: diagnostic accuracy	

Primary: the diagnostic accuracy of 18F-DOPA-PET/CT compared to 123I-MIBG scintigraphy[1]

End point title	the diagnostic accuracy of 18F-DOPA-PET/CT compared to 123I-MIBG scintigraphy[1][1]
End point description: The primary aim of this study was to evaluate the diagnostic role of 18F-DOPA PET/CT at the time of first diagnosis in children with neuroblastoma	
End point type	Primary
End point timeframe: 48 month	

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: for descriptive statistics on continuous data, the indicators used will be mean (for the point estimate) and standard deviation (for the variability of the point estimate) for categorical data used absolute and relative frequency

End point values	Neuroblastoma patients	diagnostic accuracy		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	19	19		
Units: MBq/kg megabecquerel(s)/kilogram	19	19		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

The adverse event will be notified to the Galliera Coordinating Center within 24 hours of the principal investigator becoming aware of it and subsequent relevant information will be communicated within eight days of the first report

Adverse event reporting additional description:

no adverse event reported

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16

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: no adverse event reported

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