Clinical trial results:
Molecular imaging for the early diagnosis and monitoring of Alzheimer's disease in old individuals with cognitive disturbances: an ADNI-compatible prospective study

Summary

EudraCT number	2011-004415-24
Trial protocol	IT
Global end of trial date	30 August 2013

Results information

Result version number	v1 (current)
This version publication date	28 July 2021
First version publication date	28 July 2021

Trial information

Trial identification

Sponsor protocol code	09/2011MolecularImaging

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	IRCCS CENTRO SAN GIOANNI DI DIO
Sponsor organisation address	via Pilastroni 4, Brescia, Italy,
Public contact	NA, IRCCS CENTRO SAN GIOANNI DI DIO, +39 030 3501362, gfrisoni@fatebenefratelli.it
Scientific contact	NA, IRCCS CENTRO SAN GIOANNI DI DIO, +39 030 3501362, gfrisoni@fatebenefratelli.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	07 October 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 August 2013
Global end of trial reached?	Yes
Global end of trial date	30 August 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main study objective is to expand the investigation of diagnostic and monitoring basic markers (structural MRI, tau/abeta42 levels in the CSF, FDG PET) to advanced marker, such as molecular imaging. We will use the [11C]PK11195 (pk) that represents a validated and specific PET radioligand marker of activated microglia.

Protection of trial subjects:

MRI: a questionnaire is administered to the patient prior to MRI in order to determine eligibility for the examination.
Lumbar puncture: the procedure is performed by trained personnel. The patient is kept lying and monitored for two hours after the procedure in order to avoid headache and other potential adverse events
PET: the procedure is performed by trained personnel. Special attention is paid to explaining the procedures to the patient and to allow maximization of the patient's comfort inside the scanner.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 December 2011
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: 8
Worldwide total number of subjects	8
EEA total number of subjects	8

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)	3
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The recruitment lasted from December 2011 to August 2013. It took place in two Memory Clinics in Brescia, Italy.

Pre-assignment

Screening details:

MCI patients are screened from those referred to memory clinics due to patient complaint or caregiver report of memory or other cognitive disturbance, presence of objective memory or other cognitive domain impairment and absence of functional impairment. Thirty patients refused to participate in the study.

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	PK-PET
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	[11C](R)-PK11195
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

The average radiotracer dose administered to patients was 373.6 MBq. The [11C](R)-PK11195 radiotracer was injected 30 seconds before the start of acquisitions. Data were collected in dynamic mode over 30 minutes, resulting in dynamic images of regional uptake of [11C](R)-PK11195.

Number of subjects in period 1	PK-PET
Started	8
Completed	8

Baseline characteristics

Reporting groups	
Reporting group title	PK-PET

Reporting group description: -

Reporting group values	PK-PET	Total	
Number of subjects	8	8	
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)	3	3	
From 65-84 years	5	5	
85 years and over	0	0	
Age continuous			
Mean age of 100 patients with mild cognitive impairment enrolled in the study is 68 +/- 19 years. Mean age of 8 MCI patients included in the experimental arm is 64+/- 9.			
Units: years			
arithmetic mean	64		
standard deviation	± 9	-	
Gender categorical			
The proportion of female in the PK-PET arm is 3/9 (33%)			
Units: Subjects			
Female	3	3	
Male	5	5	

End points

End points reporting groups

Reporting group title	PK-PET

Reporting group description: -

Primary: correlation between [18F]FDG-PET and [11C]-(R)-PK11195 PET.

End point title	correlation between [18F]FDG-PET and [11C]-(R)-PK11195 PET.[1]

End point description:

End point type	Primary

End point timeframe:

The statistical design was adopted to test whether the strength of the inverse correlation between microglia and metabolism was due to
the spatial overlap between the two signals.

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: Statistical analyses for the primary endpoint consists of imaging analyses that can not be filled in the web interface.

End point values	PK-PET			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: 0.804				
number (not applicable)	8			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: adverse events are collected during the entire study period	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	14

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

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 serious and non-serious adverse events occurred.

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