



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