Clinical trial results:
In-vivo assessment of nicotinic acetylcholine receptor binding in neurodegenerative diseases using the radioligand 2-[18F]FA-85380 and positron emission tomography (PET)

Summary

EudraCT number	2007-004979-19
Trial protocol	DE
Global end of trial date	01 November 2016

Results information

Result version number	v1
This version publication date	04 October 2020
First version publication date	04 October 2020
Summary attachment (see zip file)	Trial Results (A85 Folgestudie_Zusammenfassung_Ergebnisbericht_in_Arzneimittelpruefunge.._ (002).pdf)

Trial information

Trial identification

Sponsor protocol code	EK Reg.-Nr. 040-2007

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Universität Leipzig
Sponsor organisation address	Ritterstraße 26, Leipzig, Germany,
Public contact	Prof. Dr. med. Osama Sabri, Universität Leipzig Klinik und Poliklinik für Nuklearmedizin, 0049 3419718000, mbnuksekr@medizin.uni-leipzig.de
Scientific contact	Prof. Dr. med. Osama Sabri, Universität Leipzig Klinik und Poliklinik für Nuklearmedizin, 0049 3419718000, mbnuksekr@medizin.uni-leipzig.de

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	27 October 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 November 2016
Global end of trial reached?	Yes
Global end of trial date	01 November 2016
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

(1) In-vivo quantification of nicotinic acetylcholine receptor availability in neurodegenerative diseases
(2) To find diagnostic patterns of altered in-vivo nicotinic acetylcholine receptor binding in neurodegenerative disease

Protection of trial subjects:

Patients were closely monitored by the treating staff for safety during the course of the trial. This included documentation of (S)AEs as well as trial specific safety parameters.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 February 2009
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	Germany: 80
Worldwide total number of subjects	80
EEA total number of subjects	80

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)	36
From 65 to 84 years	43
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

80 patients were recruited between February 2009 and November 2016.

Pre-assignment

Screening details:

Patients were pre-screened for neurodegenerative diseases.

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Patients with neurodegenerative diseases

Arm description:

Patients with neurodegenerative diseases

Arm type	Experimental
Investigational medicinal product name	2-[18F]F-A-85380
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

One time bolus injection. The mean dose administered to trial subjects by intravenous injection was 367,1 MBq in
10 mL saline.

Arm title	Healthy Controls

Arm description: -

Arm type	Control
Investigational medicinal product name	2-[18F]F-A-85380
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

One time bolus injection. The mean dose administered to trial subjects by intravenous injection was 367,1 MBq in
10 mL saline.

Number of subjects in period 1	Patients with neurodegenerative diseases	Healthy Controls
Started	42	38
Completed	42	38

Baseline characteristics

Reporting groups	
Reporting group title	Patients with neurodegenerative diseases
Reporting group description: Patients with neurodegenerative diseases	
Reporting group title	Healthy Controls
Reporting group description: -	

Reporting group values	Patients with neurodegenerative diseases	Healthy Controls	Total
Number of subjects	42	38	80
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	14	22	36
From 65-84 years	28	15	43
85 years and over	0	1	1
Gender categorical Units: Subjects			
Female	17	20	37
Male	25	18	43

End points

End points reporting groups

Reporting group title	Patients with neurodegenerative diseases

Reporting group description:

Patients with neurodegenerative diseases

Reporting group title	Healthy Controls

Reporting group description: -

Primary: Imaging of nicotinic acetylcholine availability in neurodegenerative diseases

End point title	Imaging of nicotinic acetylcholine availability in neurodegenerative diseases[1]

End point description:

End point type	Primary

End point timeframe:

After PET Imaging.

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: Please see attached results report, the trial was stopped prematurely and thus no complete statistical analysis was performed.

End point values	Patients with neurodegenerative diseases	Healthy Controls		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	38		
Units: Whole	42	38		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: From FPI to LPO.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

Frequency threshold for reporting non-serious adverse events: 5 %

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: Please see attached results report for details on adverse events.

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