Clinical trial results:
The role of white and grey matter and meningeal inflammation in multiple sclerosis (MS) and clinically isolated syndromes (CIS) as quantified using [(11)C](R)-PK11195 positron emission tomography (PET) scanning

Summary

EudraCT number	2007-007394-22
Trial protocol	GB
Global end of trial date	03 October 2013

Results information

Result version number	v1 (current)
This version publication date	31 January 2020
First version publication date	31 January 2020
Summary attachment (see zip file)	Early termination statement (Early termination_upload_2007-007394-22_imperial.docx)

Trial information

Trial identification

Sponsor protocol code	PK11195

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Imperial College London
Sponsor organisation address	South Kensington Campus, London, United Kingdom, SW7 2AZ
Public contact	Prof PAOLA PICCINI, Imperial College London, paola.piccini@imperial.ac.uk
Scientific contact	Prof PAOLA PICCINI, Imperial College London, paola.piccini@imperial.ac.uk

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	03 October 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 October 2013
Global end of trial reached?	Yes
Global end of trial date	03 October 2013
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To determine the [(11)C](R)-PK11195 identified inflammatory response to natalizumab therapy (Tysabri) in active relapsing remitting MS.

Protection of trial subjects:

None

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 March 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	United Kingdom: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

99999 is "Not applicable" value or 0 participants, this trial was withdrawn with no participants enrolled

Pre-assignment

Screening details:

N/A

Period 1

Period 1 title	Overall (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	No intervention

Arm description: -

Arm type	no intervention
Investigational medicinal product name	no intervention
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Unknown use

Dosage and administration details:

No intervention

Number of subjects in period 1	No intervention
Started	99999
Completed	99999

Baseline characteristics

Reporting groups	
Reporting group title	Overall

Reporting group description: -

Reporting group values	Overall	Total	
Number of subjects	99999	99999	
Age categorical Units: Subjects			
no participants	99999	99999	
Age continuous Units: years			
arithmetic mean	120		
standard deviation	± 99999	-	
Gender categorical Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	No intervention

Reporting group description: -

Primary: No results

End point title	No results[1]

End point description:

End point type	Primary

End point timeframe:

N/A

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: Withdrawn study

End point values	No intervention			
Subject group type	Reporting group			
Number of subjects analysed	99999			
Units: Number	99999			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

N/A

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0

Reporting groups

Reporting group title	No intervention

Reporting group description: -

Serious adverse events	No intervention		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	No intervention		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		

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: Withdrawn study

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The withdrawn study, early termination

Notes: