



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: