



Clinical trial results:

Voidaanko S1P-reseptoreihin vaikuttamalla vähentää mikroglia-solukon aktiivisuutta ms-potilaan aivoissa? PET-tutkimus käyttäen [11C]PK11195 radioligandia

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2014-000296-12 |
| Trial protocol | FI |
| Global end of trial date | 14 June 2016 |

Results information

| | |
|-----------------------------------|---|
| Result version number | v1 (current) |
| This version publication date | 30 June 2021 |
| First version publication date | 30 June 2021 |
| Summary attachment (see zip file) | 2014-000296-12 results (Sucksdorff_2017_JNuclMed_Evaluation of the Effect of Fingolimod Treatment on Microglial Activation Using Serial PET Imaging in Multiple Sclerosis.pdf) |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | T13/2014 |
|-----------------------|----------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Turku University Hospital |
| Sponsor organisation address | kiinamylynkatu 4-8, Turku, Finland, 20520 |
| Public contact | Turku University Hospital, Turku University Hospital, +358 02 313 0000 , turkucrc@tyks.fi |
| Scientific contact | Turku University Hospital, Turku University Hospital, +358 02 313 0000 , turkucrc@tyks.fi |

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 | 29 August 2016 |
| Is this the analysis of the primary completion data? | No |

| | |
|----------------------------------|--------------|
| Global end of trial reached? | Yes |
| Global end of trial date | 14 June 2016 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate whether fingolimod-treatment has an effect on microglial activation

Protection of trial subjects:

Subjects were taken care by health care professionals during the trial visits.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 24 February 2014 |
| 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 | Finland: 11 |
| Worldwide total number of subjects | 11 |
| EEA total number of subjects | 11 |

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) | 11 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Number of screened patients: 11

Period 1

| | |
|------------------------------|----------------|
| Period 1 title | Baseline |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|--|---------------|
| Arm title | Fingolimod |
| Arm description: - | |
| Arm type | Experimental |
| Investigational medicinal product name | Gilenya |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule, hard |
| Routes of administration | Oral use |

Dosage and administration details:

Dosage and administration according to lable

| Number of subjects in period 1 | Fingolimod |
|--------------------------------|------------|
| Started | 11 |
| Completed | 11 |

Period 2

| | |
|------------------------------|----------------|
| Period 2 title | Week 6-8 |
| Is this the baseline period? | No |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|--|---------------|
| Arm title | Fingolimod |
| Arm description: - | |
| Arm type | Experimental |
| Investigational medicinal product name | Gilenya |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule, hard |
| Routes of administration | Oral use |

Dosage and administration details:

Dosage and administration according to label

| | |
|---------------------------------------|------------|
| Number of subjects in period 2 | Fingolimod |
| Started | 11 |
| Completed | 11 |

Period 3

| | |
|------------------------------|----------------|
| Period 3 title | Week 24 |
| Is this the baseline period? | No |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|--|---------------|
| Arm title | Fingolimod |
| Arm description: - | |
| Arm type | Experimental |
| Investigational medicinal product name | Gilenya |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule, hard |
| Routes of administration | Oral use |

Dosage and administration details:

Dosage and administration according to label

| Number of subjects in period 3 | Fingolimod |
|---------------------------------------|------------|
| Started | 11 |
| Completed | 11 |

Baseline characteristics

End points

End points reporting groups

| | |
|--------------------------------|------------|
| Reporting group title | Fingolimod |
| Reporting group description: - | |
| Reporting group title | Fingolimod |
| Reporting group description: - | |
| Reporting group title | Fingolimod |
| Reporting group description: - | |

Primary: Change in microglial activation between time points

| | |
|-----------------------------|---|
| End point title | Change in microglial activation between time points |
| End point description: | |
| End point type | Primary |
| End point timeframe: | |
| Baseline, Week 6-8, Week 24 | |

| End point values | Fingolimod | Fingolimod | Fingolimod | |
|-------------------------------------|-----------------|-----------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 11 | 11 | |
| Units: Distribution volume ratio | | | | |
| geometric mean (standard deviation) | 1.16 (± 0.18) | 1.04 (± 0.20) | 1.04 (± 0.13) | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Repeated-measures ANOVA with Bonferroni adjustment |
| Comparison groups | Fingolimod v Fingolimod v Fingolimod |
| Number of subjects included in analysis | 33 |
| Analysis specification | Post-hoc |
| Analysis type | other |
| P-value | < 0.05 |
| Method | ANOVA |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

24.2.2014 - 29.8.2016

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 18.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|------------|
| Reporting group title | Fingolimod |
|-----------------------|------------|

Reporting group description: -

| Serious adverse events | Fingolimod | | |
|---|----------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |

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

| Non-serious adverse events | Fingolimod | | |
|---|----------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 1 / 11 (9.09%) | | |
| General disorders and administration site conditions | | | |
| Headache | | | |
| subjects affected / exposed | 1 / 11 (9.09%) | | |
| occurrences (all) | 1 | | |

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