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	kiinamyllynkatu 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 weather fingolimodi-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 lable

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 lable

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