Clinical trial results:
Trichuris suis Oozyten (TSO®) in remittent-recurrent Multiple Sclerosis (MS) and Clinically Isolated Syndrom (CIS)

Summary

EudraCT number	2009-015319-41
Trial protocol	DE
Global end of trial date	02 March 2016

Results information

Result version number	v1 (current)
This version publication date	28 May 2022
First version publication date	28 May 2022

Trial information

Trial identification

Sponsor protocol code	TSO-MS

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Charité-Universitätsmedizin Berlin
Sponsor organisation address	Lindenberger Weg 80, Berlin, Germany, 13125
Public contact	the Department of Neurology and the NeuroCure Clinical Research Center, Charité - Universitätsmedizin Berlin, 0049 30450560284, friedemann.paul@charite.de
Scientific contact	the Department of Neurology and the NeuroCure Clinical Research Center, Charité - Universitätsmedizin Berlin, 0049 30450560284, friedemann.paul@charite.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	02 March 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	02 March 2016
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To test the efficacy of TSO® in MS and CIS patients, measured as number of new T2 lesions in cMRI after a 12 months treatment - compared to placebo.

Protection of trial subjects:

The study was approved by the local ethics committee and the German Federal Institute for Drugs and Medical Devices (BfArM).Visitation at V1-4.

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	04 February 2011
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: 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:

Individuals were recruited between September 2012 and March 2015.

Pre-assignment

Screening details:

Eleven patients diagnosed with relapsing-remitting multiple sclerosis (RRMS) according to the revised McDonald criteria [17] (CIS) with clinical activity were recruited for experimental treatment with T. suis ova (TRIOMS).

Period 1

Period 1 title	Treatment (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	TSO Group

Arm description: -

Arm type	Experimental
Investigational medicinal product name	TSO
Investigational medicinal product code	TSO
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

2500 Trichuris suis ova every 2 week for 12 months

Arm title	Placebo Group

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

every 2 weeks for 12 months

Number of subjects in period 1	TSO Group	Placebo Group
Started	5	6
Completed	5	6

Baseline characteristics

Reporting groups	
Reporting group title	TSO Group
Reporting group description: -	
Reporting group title	Placebo Group
Reporting group description: -	

Reporting group values	TSO Group	Placebo Group	Total
Number of subjects	5	6	11
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)	5	6	11
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	4	4	8
Male	1	2	3
Months since diagnosis Units: Months			
median	25	64.5	
full range (min-max)	13 to 187	5 to 165	-
EDSS score Units: Score			
arithmetic mean	1.8	2.08	
full range (min-max)	0 to 3.5	0 to 4	-
hyperintense lesions identified on T2-weighted brain MRI Units: T2 lesions			
arithmetic mean	66.75	94	
full range (min-max)	32 to 107	14 to 268	-
Gd enhancing lesions Units: Gd lesions			
median	1	1	
full range (min-max)	0 to 1	0 to 4	-

End points

End points reporting groups	
Reporting group title	TSO Group
Reporting group description: -	
Reporting group title	Placebo Group
Reporting group description: -	

Primary: T2 lesions (after final treatment)	
End point title	T2 lesions (after final treatment)
End point description: for more details see attached PMID (table 1, page 5)	
End point type	Primary
End point timeframe: 12 months	

End point values	TSO Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	6		
Units: Score				
median (full range (min-max))	53 (15 to 268)	67.5 (36 to 105)		

Statistical analyses

Statistical analysis title	Lesion change over 12 months
Comparison groups	TSO Group v Placebo Group
Number of subjects included in analysis	11
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)

Secondary: Gd enhancing lesions (after final treatment)	
End point title	Gd enhancing lesions (after final treatment)
End point description: For more detail see attached PMID	
End point type	Secondary
End point timeframe: 12 months	

End point values	TSO Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	6		
Units: Score				
median (full range (min-max))	0 (0 to 1)	0 (0 to 2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of relapses

End point title	Number of relapses

End point description:

End point type	Secondary

End point timeframe:

12 months (V0-V4)

End point values	TSO Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	6		
Units: Count				
median (full range (min-max))	0 (0 to 3)	1 (0 to 2)		

Statistical analyses

No statistical analyses for this end point

Secondary: EDSS score (after final treatment)

End point title	EDSS score (after final treatment)

End point description:

End point type	Secondary

End point timeframe:

12 months

End point values	TSO Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	6		
Units: Score				
median (full range (min-max))	1.5 (0 to 2)	2.75 (0 to 4)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 12 months	
Assessment type	Systematic

Dictionary used	
Dictionary name	own
Dictionary version	1

Reporting groups	
Reporting group title	TSO Group
Reporting group description: -	
Reporting group title	Placebo Group
Reporting group description: -	

Serious adverse events	TSO Group	Placebo Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	TSO Group	Placebo Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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: no AEs were reported

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.

Recruitment problems due to considerable reservations about worm egg therapy by patients in some cases and because of the considerable expansion of therapy options in the treatment of MS with orally available substances within the recruitment period.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/33572978