



Clinical trial results:

The HAM Ciclosporin Study: An observational trial of therapy in early or progressing HAM/TSP

Summary

EudraCT number	2006-002031-24
Trial protocol	GB
Global end of trial date	29 January 2010

Results information

Result version number	v1 (current)
This version publication date	16 October 2019
First version publication date	16 October 2019

Trial information

Trial identification

Sponsor protocol code	HAM005
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00773292
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 Graham Taylor, Imperial College London, +44 020 3312 1521, g.p.taylor@imperial.ac.uk
Scientific contact	Prof Graham Taylor, Imperial College London, +44 020 3312 1521, g.p.taylor@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	24 January 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 January 2010
Global end of trial reached?	Yes
Global end of trial date	29 January 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine in an open, pilot, proof of principle study whether ciclosporin A improves the clinical measures of patients with 'early' or 'progressing' 'definite' HAM/TSP

Protection of trial subjects:

None

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 2006
Long term follow-up planned	Yes
Long term follow-up rationale	Scientific research
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 7
Worldwide total number of subjects	7
EEA total number of subjects	7

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)	6
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

All patients attended to National Centre for Human Retrovirology at St Mary's Hospital, London.

Pre-assignment

Screening details:

Eligible patients had definite HAM/TSP, as defined by 'Belem criteria' and either had developed first symptoms within the last two years or had progressive disease, as defined by 50% documented deterioration in 10 m timed walk over the preceding three months.

Period 1

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

Arms

Arm title	All participants
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Arm description:

4 weeks treatment

Arm type	Experimental
Investigational medicinal product name	None
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

No treatment in the pre-treatment period

Number of subjects in period 1	All participants
Started	7
Completed	7

Period 2

Period 2 title	Treatment
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	All participants
Arm description:	
48 weeks treatment	
Arm type	Experimental
Investigational medicinal product name	Ciclosporin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
2.5 - 5mg/kg/day in two equally divided doses. dose adjusted according to trough ciclosporin concentration	

Number of subjects in period 2	All participants
Started	7
Completed	5
Not completed	2
Adverse event, non-fatal	1
Lack of efficacy	1

Period 3	
Period 3 title	Post treatment follow up
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded
Arms	
Arm title	All participants
Arm description:	
24 weeks treatment	
Arm type	Experimental
Investigational medicinal product name	None
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
No treatment in the pre-treatment period	

Number of subjects in period 3	All participants
Started	5
Completed	7

Joined	2
stayed on the study,even they didnt finish treatme	2

Baseline characteristics

Reporting groups

Reporting group title	Pre - Treatment
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Reporting group description: -

Reporting group values	Pre - Treatment	Total	
Number of subjects	7	7	
Age categorical			
Units: Subjects			
Adults (18-64 years)	6	6	
From 65-84 years	1	1	
Age continuous			
Units: years			
median	50		
full range (min-max)	40 to 69	-	
Gender categorical			
Units: Subjects			
Female	2	2	
Male	5	5	

End points

End points reporting groups

Reporting group title	All participants
Reporting group description:	
4 weeks treatment	
Reporting group title	All participants
Reporting group description:	
48 weeks treatment	
Reporting group title	All participants
Reporting group description:	
24 weeks treatment	

Primary: Number of Patient With Lack of Objective Clinical Improvement

End point title	Number of Patient With Lack of Objective Clinical
End point description:	
Lack of objective clinical improvement after three months of therapy. Objective improvement was defined as any of the following comparing baseline measurements to 12, 24 and 48 weeks: i) one point decrease in the IPEC 1 scale (Instituto de Pesquisa Clínica Evandro Chagas), ii) >30% improvement in 10 m timed walk, iii) visual analogue pain score reduced by >2 points, iv) reduction of frequency or nocturia by greater than one or reduction of residual volume by more than 10% at two consecutive visits.	
Proof of concept study and therefore outcomes report is descriptive only. No statistical test appropriate.	
End point type	Primary
End point timeframe:	
12 month	
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: Proof of concept study and therefore outcomes report is descriptive only. No statistical test appropriate. Please see attached article.	

End point values	All participants			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: number of participant	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Changes in Clinical Outcome Measures, Time Walk at 12 Weeks Compared to Baseline

End point title	Changes in Clinical Outcome Measures, Time Walk at 12 Weeks Compared to Baseline
End point description:	
Change in the time taken to walk 10 meters 0 - 12 weeks compared with baseline. A timed walk rank was created to take into account the use of walking aids.	

Timed walk rank was calculated by ranking the time to walk 10 meters over all patients and visits, in the following order (highest/worst score to lowest/best score): unable to walk; able to walk, but not able to complete 10 meters (ranked on distance walked and time taken); able to walk 10 meters with a bilateral aid; able to walk 10 meters with a unilateral aid; able to walk 10 meters unaided (all ranked on time taken).

Decrease in score means improvement.

End point type	Secondary
End point timeframe:	
12 weeks	

End point values	All participants			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: score				
geometric mean (standard deviation)	-7 ($\pm$ 5)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

72 weeks

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	10
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Reporting groups

Reporting group title	All participants
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Reporting group description:

4 weeks treatment

Serious adverse events	All participants		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (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	All participants		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 7 (14.29%)		
Nervous system disorders			
Tremor			
subjects affected / exposed	1 / 7 (14.29%)		
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

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/2272010>