Clinical trial results:
A phase 2, double-blind, placebo-controlled study of the safety and tolerability of etanercept in patients with Alzheimer's disease

Summary

EudraCT number	2009-013400-31
Trial protocol	GB
Global end of trial date	30 August 2013

Results information

Result version number	v1 (current)
This version publication date	15 August 2020
First version publication date	15 August 2020
Summary attachment (see zip file)	Summary (2009-013400-31_result_summary.pdf)

Trial information

Trial identification

Sponsor protocol code	STEADI-09

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01068353
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University of Southampton
Sponsor organisation address	University Rd , Southampton , United Kingdom, SO17 1BJ
Public contact	Clive Holmes, University of Southampton, c.holmes@soton.ac.uk
Scientific contact	Clive Holmes, University of Southampton, c.holmes@soton.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	30 August 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 August 2013
Global end of trial reached?	Yes
Global end of trial date	30 August 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

In patients with mild to moderate Alzheimer's disease, is treatment with etanercept, when compared with placebo, safe and well tolerated over a 6-month period?

Protection of trial subjects:	
None	
Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	25 January 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 41
Worldwide total number of subjects	41
EEA total number of subjects	41

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)	0
From 65 to 84 years	41
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The protocol and consent forms were approved by a multicenter research ethics committee (Southampton and South West Hampshire REC [A], reference number 10/H0502).

Pre-assignment

Screening details:

All participants provided informed consent before screening procedures.

Period 1

Period 1 title	Overall (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	Etanercept
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Etanercept
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

50 mg once weekly for 24 weeks

Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo once weekly for 24 weeks

Number of subjects in period 1	Etanercept	Placebo
Started	20	21
Completed	18	15
Not completed	2	6
Consent withdrawn by subject	1	1
Adverse event, non-fatal	1	5

Baseline characteristics

Reporting groups	
Reporting group title	Etanercept
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Reporting group values	Etanercept	Placebo	Total
Number of subjects	20	21	41
Age categorical Units: Subjects			
From 65-84 years	20	21	41
Age continuous Units: years			
arithmetic mean	72	72.9	
standard deviation	± 2.1	± 2.2	-
Gender categorical Units: Subjects			
Female	5	11	16
Male	15	10	25
ADAS-cog 5 Alzheimer's Disease Assessment Scale–cognitive Units: score			
arithmetic mean	25.8	25.7	
standard deviation	± 2.9	± 2.5	-

End points

End points reporting groups

Reporting group title	Etanercept
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Primary: Changes in sMMSE 5 standardized Mini-Mental State Examinationscores compare the baseline to 12 weeks and 24 weeks

End point title	Changes in sMMSE 5 standardized Mini-Mental State Examinationscores compare the baseline to 12 weeks and 24 weeks
End point description:	
End point type	Primary
End point timeframe:	
24 weeks	

End point values	Etanercept	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	15		
Units: score				
arithmetic mean (standard error)	-0.1 (± 0.5)	-1.9 (± 1.2)		

Statistical analyses

Statistical analysis title	sMME
Comparison groups	Etanercept v Placebo
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.07
Method	t-test, 2-sided

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 24 weeks	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	10

Reporting groups	
Reporting group title	Etanercept
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Serious adverse events	Etanercept	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Renal and urinary disorders			
Urinary tract infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Etanercept	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 20 (100.00%)	21 / 21 (100.00%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 20 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	2	
General disorders and administration site conditions			
Fatigue			

subjects affected / exposed	1 / 20 (5.00%)	1 / 21 (4.76%)	
occurrences (all)	1	1	
Respiratory, thoracic and mediastinal disorders			
Yawning			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
Sleep disorder			
subjects affected / exposed	3 / 20 (15.00%)	5 / 21 (23.81%)	
occurrences (all)	3	6	
Investigations			
Gastroenteritis			
subjects affected / exposed	9 / 20 (45.00%)	6 / 21 (28.57%)	
occurrences (all)	11	7	
Cardiac disorders			
Arterial disorder			
subjects affected / exposed	2 / 20 (10.00%)	2 / 21 (9.52%)	
occurrences (all)	2	2	
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 20 (10.00%)	2 / 21 (9.52%)	
occurrences (all)	2	2	
Blood and lymphatic system disorders			
Normocytic anaemia			
subjects affected / exposed	0 / 20 (0.00%)	3 / 21 (14.29%)	
occurrences (all)	0	3	
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 20 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	2	
Eye disorders			
Pain			
subjects affected / exposed	0 / 20 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	2	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	5 / 20 (25.00%)	5 / 21 (23.81%)	
occurrences (all)	5	7	

Skin and subcutaneous tissue disorders Dermatitis subjects affected / exposed occurrences (all)	 1 / 20 (5.00%) 1	 3 / 21 (14.29%) 4	
Renal and urinary disorders Incontinence subjects affected / exposed occurrences (all)	 1 / 20 (5.00%) 1	 1 / 21 (4.76%) 1	
Musculoskeletal and connective tissue disorders Pain subjects affected / exposed occurrences (all)	 1 / 20 (5.00%) 1	 3 / 21 (14.29%) 5	
Infections and infestations Local reaction subjects affected / exposed occurrences (all)	 2 / 20 (10.00%) 4	 1 / 21 (4.76%) 1	
Metabolism and nutrition disorders Dehydration subjects affected / exposed occurrences (all)	 1 / 20 (5.00%) 2	 1 / 21 (4.76%) 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/25934853