ISRCTN89039808 https://doi.org/10.1186/ISRCTN89039808

Efficacy and safety of S 38093 versus placebo in patients with mild to moderate Alzheimer's disease

Submission date	Recruitment status	[X] Prospectively registered
20/05/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/07/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/04/2020	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration and not expected to be available in the future

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2010-024626-37

Protocol serial number
CL2-38093-011

Study information

Scientific Title
Efficacy and safety of three doses of S 38093 (2, 5 and 20 mg/day) versus placebo in patients with mild to moderate Alzheimer's disease

Study objectives
To demonstrate efficacy of at least one dose of S 38093 as compared to placebo on primary endpoint

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained before recruitment of the first participants

Study design
A 24-week international, multi-centre, randomised, double-blind, placebo-controlled phase IIb study followed by a 24-week extension period

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild to moderate Alzheimer's disease

Interventions
1. 2, 5 or 20mg/day of S 38093 or placebo, orally, during a 24-week treatment period + 24-week treatment extension period
2. A 2-6-week selection period without study treatment will be followed by a 24-week double-blind treatment with 4-parallel groups (doses : 2, 5 and 20 mg/day of S38093 and placebo) and a 24-week optional treatment extension period (patients on placebo will be re-randomised to S 38093 2; 5 or 20mg) and a 2-week follow-up period
3. One tablet of S 38093 (2, 5 or 20mg) or placebo will be taken orally, once a day, during study participation from inclusion visit +1 until follow-up period

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
S 38093

Primary outcome(s)
1. The Alzheimer's Disease Assessment Scale-Cognitive subscale (ADAS-Cog) 11-items 2. ADAS-Cog will be assessed at week 0, week 24, week 36 and week 48

Key secondary outcome(s))
1. Disability Assessment for Dementia (DAD)
2. DAD will be assessed at week 0, week 24 and week 48

Completion date
30/04/2014

Eligibility

Key inclusion criteria
1. Age 55-85 years
2. School education more than or equal to 4 years
3. Able to perform neuropsychological tests
4. Have adequate visual and auditory acuity with the usual corrective aids to allow neuropsychological testing
5. Have a responsible informant Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision (DSM-IV-TR) criteria for Dementia of the Alzheimer's type
6. National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) criteria for probable Alzheimer's disease (AD)
7. Mini-Mental State Examination (MMSE) between 15 and 24

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
711

Key exclusion criteria
1. Inpatients
2. Female patients of child-bearing potential
3. Dementia due to any condition other than AD
4. History of epilepsy or solitary seizure
5. History or presence of Parkinson's disease or Parkinsonism
6. Major neurological or neurodegenerative conditions associated with significant cognitive impairment such as Multiple Sclerosis or Huntington's Disease
7. Major psychiatric conditions

Date of first enrolment
22/08/2011

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
Australia

Brazil

Bulgaria

Chile

Czech Republic

France

Germany

Hungary

Mexico

Portugal

Romania

Russian Federation

South Africa

Study participating centre
CHU La Grave-Casselardit
Toulouse
France
31059

Sponsor information

Organisation
Institut de Recherches Internationales Servier (France)

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Institut de Recherches Internationales Servier (France)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from https://clinicaltrials.servier.com if a Marketing Authorisation has been granted after 1st January 2014.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
Basic results			20/04/2020	No	No