Efficacy and Safety of Memantine Hydrochloride, a low affinity antagonist to NMethyl-D-Aspartate (NMDA) type receptors, in the prevention of cognitive decline and disease progression in older people with Down's syndrome, with and without dementia

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
28/02/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
16/05/2005	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
23/02/2012	Nervous System Diseases			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Marisa Lana

Contact details

King's College London Wolfson Research Center for Age Related Diseases Guy's Campus London United Kingdom SE1 1UL +44 (0)7810481267 lana@onetel.com

Additional identifiers

Clinical Trials Information System (CTIS)

ClinicalTrials.gov (NCT)

NCT00240760

Protocol serial number

KCL/DS/MEM/1

Study information

Scientific Title

Acronym

MEADOWS study

Study objectives

This is a prospective, fifty-two week, multicentre, randomised, double-blind, placebo-controlled parallel group clinical trial in people with Down's syndrome and/or dementia. The study is designed to evaluate the efficacy, safety and tolerability of memantine in this population.

Primary Aims:

- 1. Clinical: To determine the clinical efficacy of memantine versus placebo in preventing cognitive decline in people with Down's syndrome (DS). To compare the safety and tolerability of memantine versus placebo in people with Down's syndrome (DS).
- 2. Biochemical and pathological: To examine the ability of memantine to alter markers of disease progression in DS patients.

Secondary Aims:

- 1. Clinical: To determine whether memantine has, as compared with placebo, a significant positive impact on: the independent functioning level as measured by the carer-rated adaptive behavioural scale, (ABS) in adults with Down's syndrome suffering from dementia, quality of life in adults with Down's syndrome suffering from dementia.
- 2. Biochemical and pathological: To investigate putative markers of memantine's mechanism of action in peripheral samples from living patients with DS.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Health condition(s) or problem(s) studied

Cognitive decline and dementia in Down's syndrome

Interventions

Randomized, double blind, placebo controlled trial of Memantine versus placebo to assess the safety and efficacy of Memantine in preventing cognitive decline in adults with Down syndrome; effect of memantine on key progression disease markers of Alzheimer's disease in Down's syndrome.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

memantine

Primary outcome(s)

Comparing Memantine to placebo. Changes in performance from baseline on a neuropsychological battery of tests for people with DS focussing upon 3 cognitive areas: attention, memory and executive function (the DAME, battery).

Key secondary outcome(s))

Comparing Memantine to placebo:

- 1. Incidence of dementia (International Statistical Classification of Diseases and Related Health Problems tenth revision [ICD-10] criteria)
- 2. Changes in performance from baseline on the Adaptive Behavioural Scale (ABS)
- 3. Changes in performance from baseline on quality of life (QOL-AD)
- 4. Changes in performance from baseline on Clinical Global Impression of Change
- 5. Changes in key biomarkers

Completion date

31/07/2006

Eligibility

Key inclusion criteria

People with Down's syndrome over the age of 40 and/or dementia

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/07/2005

Date of final enrolment

31/07/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre King's College London

London United Kingdom SE1 1UL

Sponsor information

Organisation

King's College London (UK)

ROR

https://ror.org/0220mzb33

Funder(s)

Funder type

Industry

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created Date added	Peer reviewed?	Patient-facing?
Results article	results	11/02/2012	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes