

Efficacy and Safety of Memantine Hydrochloride, a low affinity antagonist to N-Methyl-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 28/02/2005	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 16/05/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/02/2012	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

ClinicalTrials.gov (NCT)

NCT00240760

Clinical Trials Information System (CTIS)

2005-000381-39

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, age over 40 and 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)

Not Specified

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

Lundbeck

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