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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

Registration date
16/05/2005

Last Edited
23/02/2012

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Primary study design
Interventional

Study design
Randomised controlled trial

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

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