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Genetically determined brain abnormalities in Down's syndrome - towards a treatment: Down's syndrome Lithium Trial

Submission date	Recruitment status	[_] Prospectively registered
28/05/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/08/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/05/2019	Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2008-008342-20

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Sponsor ID: RAA08-015; EudraCT number: 2008-008342-20

Study information

Scientific Title
Genetically determined brain abnormalities in Down's syndrome - towards a treatment: a randomised, single-blind, placebo-controlled trial of lithium carbonate in Down's syndrome

Acronym
DOWNSLIT

Study objectives
That brain myo-inositol levels in non-demented Down's syndrome individuals can be reduced by a 4-week trial of lithium carbonate at therapeutic doses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Research Ethics Committee, 23/02/2009, ref: 09/H1102/3

Study design
Single-centre randomised single-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Down's syndrome

Interventions
Lithium carbonate (Camcolit®), 250 mg oral tablets versus placebo.

Titration phase: dose adjusted to achieve therapeutic plasma level of 0.4-1.0 mmol/l
Maintenance phase: twice daily dosing for 4 weeks on therapeutic lithium carbonate dose
Titration phase: dose adjusted to achieve therapeutic plasma level of 0.4-1.0mmol/L
Maintenance phase: twice daily dosing for 4 weeks on therapeutic lithium carbonate dose

Total duration of treatment is around 8 weeks; follow-up will be as appropriate if patients have any side-efects on lithium, otherwise patient involvement ends when they come off the medication. Likewise for placebo group.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Lithium carbonate (Camcolit®)

Primary outcome measure
Brain myo-inositol concentrations (dorsolateral prefrontal cortex [DLPFC] and hippocampus) measured by 1H magnetic resonance spectroscopy (MRS) at baseline and after 4 weeks maintenance lithium treatment at therapeutic dose.

Secondary outcome measures
1. Blood biomarkers which have been implicated in the development of Alzheimer's disease:
1.1. Isolation of genomic DNA for studies of genotype in relation to response including the Tau haplotype, Intron 7 repeat of APP, and ApoE4
1.2. Abeta1-40, Abeta1-42 base fragments and other amyloid species
1.3. Markers of amyloid oxidative stress e.g. isoprostane and other members
1.4. Markers of systemic inflammation e.g. IL-6, TNF-alpha and other inflammatory markers
1.5. Other markers of APP processing e.g. BACE
2. Cognitive measures:
2.1. British Picture Vocabulary Scale (BPVS) at baseline
2.2. Cambridge Examination for mental disorders of the elderly revised (CAMDEX-R) section on Cognitive Examination (CAMCOG) after 4 weeks maintenance lithium treatment at therapeutic dose

Overall study start date
01/06/2009

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Individuals with Down's syndrome
2. Over the age of 18 years, either sex
3. Able to provide informed consent for themselves or have a representative to provide proxy consent on their behalf if they lack capacity
4. Able to communicate with the investigator and to comply with requirements of the study
5. Has carer support

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
34

Total final enrolment
19

Key exclusion criteria
1. Individuals with contraindications to lithium treatment
2. Individuals with contraindications to undergoing a magnetic resonance scan
3. Non-compliance with taking of the tablets between baseline and the final assessment
4. Treatment with lithium within the last 6 months
5. Evidence of dementia
6. Evidence of renal, thyroid or cardiac disease that would contraindicate taking lithium
7. Pregnancy

Date of first enrolment
01/06/2009

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Professor of Psychiatry and Brain Maturation
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London (UK)

Sponsor details
c/o Professor Peter McGuffin
Dean and Head of School
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Sponsor type
University/education

Website
http://www.iop.kcl.ac.uk/

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Baily Thomas Charitable Fund (UK) (ref: 2215/1)

Alternative Name(s)
The Baily Thomas Charitable Fund

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Basic results			20/05/2019	No	No
HRA research summary			28/06/2023	No	No