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Imaging the neural correlates of rehabilitation in Wernicke's aphasia

Submission date
10/11/2006

Recruitment status
No longer recruiting

Registration date
04/12/2006

Overall study status
Completed

Last Edited
06/03/2017

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Around one in three people experience some degree of aphasia after having a stroke. Aphasia is caused by damage to parts of the brain responsible for understanding and using language. In Wernicke's aphasia, a person is able to speak normally and use long, complex sentences, but the actual words they use do not make sense, or they include nonsense words in their speech. The aim of this study is to measure therapy-related changes in brain function in a group of patients with post-stroke Wernicke's aphasia. Two therapies will be trialled: a drug (donepezil) and a computer-delivered speech therapy programme.

Who can participate?
Men and women over the age of 18 with Wernicke's aphasia who had a stroke more than three months ago.

What does the study involve?
Each patient will be randomly allocated to one of two groups. Group one will take donezepil once daily for five weeks; if this is well tolerated then the dose will be increased. Group two will take a placebo (dummy). After a five-week break, group one will take the placebo and group two will take donezepil. A five-week behavioural therapy treatment will also be provided to both groups, which will be performed by the patients at their home and will consist of 30 minutes of a computer-based speech therapy programme once a day.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Wellcome Department of Imaging Neuroscience (UK)

When is the study starting and how long is it expected to run for?
October 2006 to January 2010

Who is funding the study?
The Wellcome Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2005-004215-30

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
075765; ME033459MES

Study information

Scientific Title
Imaging the neural correlates of cholinergic and behaviour driven rehabilitation in patients with Wernicke's aphasia: a double-blinded, cross-over, randomised controlled trial

Study objectives
To measure therapy related changes in brain function in a group of patients with post-stroke, Wernicke's aphasia. Two therapies will be trialed: a drug (donepezil) and computer-delivered speech therapy programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Hospital for Neurology and Neurosurgery and the Institute of Neurology Joint REC, 06/01/2006, ref: 05/Q0512/134

Study design
Double-blinded cross-over randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Post-stroke aphasia

Interventions
This is a cross-over trial. Each patient will be randomised to one of the two groups:
Group one: donezepil (5 mg) once daily (od) for five weeks (block one), if this is well tolerated then this will be increased to 10 mg od for five weeks (block two).
Group two: an identical placebo will be provided, to be used in the exact same method as above (blocks four and five).

In between the two groups (block three), there will be a washout period of five weeks.

At blocks two and five, a non drug intervention will also be supplied. During these times, a five week Behavioural Therapy (BT) treatment will also be provided, which will be performed by the patients at their home, and will consist of 30 minutes of a computer-based phonological training program once a day.

Intervention Type
Mixed

Primary outcome measure
Correlation between treatment type and changes in the response characteristics of a neurophysiologic measure of auditory discrimination (Mismatch Negativity [MMN]), provoked by language and non-language stimuli, measured using both MEG and fMRI.

Secondary outcome measures

Correlation between treatment type and improvements on a language rating scale: the Comprehensive Aphasia Test.

Overall study start date
01/10/2006

Completion date
14/01/2010

Eligibility

Key inclusion criteria
1. Subjects will be English native speakers
2. Subjects will be over the age of 18, either sex
3. More than three months post stroke
4. Only consent competent patients will be enrolled

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
~30

Key exclusion criteria
1. Patients with contraindications to cholinesterase inhibitors
2. Patients with contraindications to functional Magnetic Resonance Imaging (fMRI) /Magnetoencephalography (MEG)
3. Significant medical or psychiatric co-morbidity
4. Under 18 years old

Date of first enrolment
01/10/2006

Date of final enrolment
30/07/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wellcome Department of Imaging Neuroscience
London
United Kingdom
WC1N 3BG

Sponsor information

Organisation
Joint UCLH and UCL Biomedical Research Unit (UK)

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Sponsor type
Not defined

Website
http://www.ucl.ac.uk/biomed-r-d/general/about_us.htm#contact

ROR
https://ror.org/03r9qc142

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (grant ref: 075765)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The main (longitudinal) result is in review and will be published in the next 6 months. Another paper (secondary outcomes) should be submitted in the next 6 months.

Intention to publish date
07/03/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	baseline data	01/06/2011		Yes	No
Other publications	baseline data	21/03/2012		Yes	No
Other publications	baseline data	01/06/2013		Yes	No
Results article	results	01/07/2017		Yes	No