

Imaging the neural correlates of rehabilitation in Wernicke's aphasia

Submission date 10/11/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 04/12/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 06/03/2017	Condition category Signs and Symptoms	☐ 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 donepezil 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 donepezil. 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

Clinical Trials Information System (CTIS)
2005-004215-30

Protocol serial number
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

Study type(s)

Treatment

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: donepezil (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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Wellcome Department of Imaging Neuroscience

London

United Kingdom

WC1N 3BG

Sponsor information

Organisation

Joint UCLH and UCL Biomedical Research Unit (UK)

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

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?
Results article	results	01/07/2017		Yes	No
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