

# Imaging the neural correlates of rehabilitation in Wernicke's aphasia

<b>Submission date</b> 10/11/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/12/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/03/2017	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> 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?  
Dr Alexander Paul Leff  
a.leff@fil.ion.ucl.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Alexander Paul Leff

**ORCID ID**  
<http://orcid.org/0000-0002-0831-3541>

**Contact details**  
Wellcome Department of Imaging Neuroscience  
12 Queen Square  
London  
United Kingdom  
WC1N 3BG  
+44 (0)20 7833 7472  
a.leff@fil.ion.ucl.ac.uk

## 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: 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 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)

**Sponsor details**

c/o Dr Victoria Latter, Operations Director

1st Floor, Maple House

149 Tottenham Court Road

London

United Kingdom

W1P 9LL

+44 (0)20 7472 6394

v.latter@medsch.ucl.ac.uk

**Sponsor type**

Not defined

**Website**

[http://www.ucl.ac.uk/biomed-r-d/general/about\\_us.htm#contact](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?
<a href="#">Other publications</a>	baseline data	01/06/2011		Yes	No
<a href="#">Other publications</a>	baseline data	21/03/2012		Yes	No
<a href="#">Other publications</a>	baseline data	01/06/2013		Yes	No
<a href="#">Results article</a>	results	01/07/2017		Yes	No