

# Open-label pilot study of memantine in chronic cough patients attending a specialist clinic

<b>Submission date</b> 05/09/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/09/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/06/2020	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

People cough in order to clear their airways. Most coughs are caused by viruses and settle down by themselves, but some people develop persistent coughing which can last for many years. This is called chronic cough. People with chronic cough find the symptom very upsetting and it can have a major impact on their quality of life. There are currently no effective treatments for chronic cough. This study aims to investigate whether a drug called Memantine helps to reduce coughing. Memantine is a similar medication to that found in many over the counter treatments for cough (Dextromethorphan). Memantine is currently licensed to treat patients with Alzheimer's disease. It has never been tested on patients with chronic cough.

### Who can participate?

People aged 18 - 90 with chronic cough.

### What does the study involve?

Fifteen patients attending the specialist chronic cough service at Wythenshawe Hospital will be invited to attend the North West Lung Research Centre up to 7 times over a maximum 8-week period. During the course of the study they will be asked to take increasing doses of Memantine, have a blood test, electrocardiogram (recording the electrical activity of the heart), undergo 24-hour cough monitoring, and answer cough-related questionnaires.

### What are the possible benefits and risks of participating?

Not provided at time of registration.

### Where is the study run from?

North West Lung Research Centre at Wythenshawe Hospital (UK).

### When is the study starting and how long is it expected to run for?

September 2012 to March 2013.

### Who is funding the study?

Medical Research Council (UK).

Who is the main contact?  
Danielle Yuill  
danielle.yuill@manchester.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Miss Danielle Yuill

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-  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
2011-005151-13

**Protocol serial number**  
12508

## Study information

**Scientific Title**  
Open-label pilot study of memantine in chronic cough patients attending a specialist clinic

**Study objectives**  
This study aims to investigate whether a drug called Memantine helps to reduce coughing.

More details can be found at <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=12508>

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
NRES Committee North West - Haydock, 20/12/2011 ref: 11/NW/0840

**Study design**  
Non-randomised interventional trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Chronic cough

**Interventions**

Memantine, escalating dose from 10 mg/day to 40 mg/day

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Memantine

**Primary outcome(s)**

To evaluate the change in objectively recorded cough frequency in chronic cough patients after treatment

**Key secondary outcome(s)**

No secondary outcome measures

**Completion date**

01/03/2013

**Eligibility**

**Key inclusion criteria**

1. Chronic cough (>8 weeks)
2. Normal chest x-ray
3. FEV1 and FVC >70% predicted measured using spirometry
4. Idiopathic or treatment resistant chronic cough, defined as a cough for which no objective evidence of an underlying trigger can be determined after routine clinical investigation (idiopathic) or a cough that did not respond to standard treatment for identified underlying triggers (treatment-resistant)
5. Females will be non-pregnant and non-lactating with no intention of pregnancy during study treatment
6. Male and female participants aged 18 - 90 years

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

90 years

**Sex**

All

**Total final enrolment**

14

**Key exclusion criteria**

1. Recent upper respiratory tract infection (<4 weeks)
2. Pregnancy/breastfeeding. Women of childbearing potential (not >2 years postmenopausal and /or not surgically sterilised) must have a negative blood serum pregnancy test, performed at visit 1 prior to administration of study medication
3. Current smokers or ex-smokers with <6 months abstinence or cumulative history of >10 pack years
4. Current treatment with ACE inhibitors
5. Drug or alcohol abuse
6. Uncontrolled hypertension (i.e., >140/90 mmHg despite adequate medical therapy)
7. Recent myocardial infarction, or history of congestive cardiac failure
8. Any clinically significant neurological disorder
9. Prior renal transplant, current renal dialysis, patients with creatinine clearance <30ml/min or history of renal tubular acidosis
10. Severe hepatic impairment
11. Fructose intolerance
12. Any clinically significant or unstable medical or psychiatric condition that would interfere with the patient's ability to participate in the study

**Date of first enrolment**

03/09/2012

**Date of final enrolment**

01/03/2013

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Wythenshawe Hospital**  
Manchester  
United Kingdom  
M23 9LT

## Sponsor information

### Organisation

University Hospital of South Manchester (UK)

### ROR

<https://ror.org/00he80998>

## Funder(s)

### Funder type

Research council

### Funder Name

Medical Research Council [MRC] ref: G0701918 (UK) ID #87018

### Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## 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?
<a href="#">Basic results</a>			23/06/2020	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No