ISRCTN99941214 https://doi.org/10.1186/ISRCTN99941214

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

Submission date	Recruitment status	[_] Prospectively registered
05/09/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/09/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/06/2020	Signs and Symptoms	

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 reduces 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

Contact details
Wythenshawe Hospital
Southmoor Road
Manchester
United Kingdom
M23 9LT
-
danielle.yuill@manchester.ac.uk

Additional identifiers

EudraCT/CTIS number
2011-005151-13

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 reduces 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

Secondary study design
Non randomised study

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

Secondary outcome measures
No secondary outcome measures

Overall study start date
03/09/2012

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
UK Sample Size: 15

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
England

United Kingdom

Study participating centre
Wythenshawe Hospital
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
University Hospital of South Manchester (UK)

Sponsor details
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
England
United Kingdom
M23 9LT

Sponsor type
Hospital/treatment centre

Website
http://www.uhsm.nhs.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, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

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			23/06/2020	No	No
HRA research summary			28/06/2023	No	No