# The effect of Naltrexone, an Opiate Receptor Antagonist, on capsaicin dose-response in male Healthy volunteers (NORAH)

<b>Submission date</b> 05/09/2012	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>
		☐ Protocol
Registration date Ove	Overall study status	Statistical analysis plan
10/09/2012	Completed	Results
Last Edited	Condition category Respiratory	Individual participant data
07/12/2017		<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Background and study aims

Coughing is extremely common and has a major impact on quality of life. Some people develop persistent coughing (more than 8 weeks in duration) which is called chronic cough. The current treatments for chronic cough are not effective. To develop better treatments we would like to understand how coughing can normally be controlled in healthy people. Coughing can be induced by breathing in an extract of chilli pepper (called capsaicin). This is entirely safe, and has been used in several research studies. Our previous research has shown that healthy people tend to cough much less than patients with a cough after they have inhaled capsaicin, but we do not yet understand why this is. We believe that when healthy people inhale capsaicin, morphine-like substances may be released in the brain. These morphine-like substances may reduce coughing by acting on certain brain receptors, known as opiate receptors. We think that by blocking these opiate receptors using a drug called naltrexone, healthy people would temporarily cough more than usual.

# Who can participate?

We will need 15 male healthy volunteers to take part in this study.

# What does the study involve?

The study will involve two visits at least 1 week apart. Each visit will last about 2 hours. At one of the visits, the volunteer will take a tablet containing naltrexone, and at the other visit the volunteer will take a tablet that contains no active drug (called a placebo). The study doctor will not know which tablet the volunteer takes during the study visits (known as blinding). During each visit the volunteer will inhale capsaicin so that we can measure how much they cough and be asked to complete a questionnaire about their urge to cough.

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? August 2012 to April 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

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# Additional identifiers

Protocol serial number 12506

# Study information

#### Scientific Title

The effect of Naltrexone, an Opiate Receptor Antagonist, on capsaicin dose-response in male Healthy volunteers (NORAH)

#### **Acronym**

**NORAH** 

# Study objectives

Coughing is extremely common and has a major impact on quality of life. Some people develop persistent coughing (more than 8 weeks in duration) which is called chronic cough. Current treatments for chronic cough are ineffective. To develop better treatments we would like to understand how coughing can normally be controlled in healthy people. Coughing can be induced by breathing in an extract of chilli pepper (called capsaicin). This is entirely safe, and has been used in several research studies. Our previous research has shown that healthy people tend to cough much less than patients with a cough after they have inhaled capsaicin, but we do

not yet understand why this is. We believe that when healthy people inhale capsaicin, morphine-like substances may be released in the brain. These morphine-like substances may reduce coughing by acting on certain brain receptors, known as opiate receptors. We think that by blocking these opiate receptors using a drug called naltrexone, healthy people would temporarily cough more than usual.

More details can be found at http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=12506

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

NRES Committee North West - Greater Manchester South, 21/05/2012 ref: 12/NW/0293

#### Study design

Randomised interventional trial

# Primary study design

Interventional

## Study type(s)

Treatment

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

Chronic cough

#### **Interventions**

Naltrexone, 50 mg naltrexone tablet or placebo administered to volunteers

#### Intervention Type

Drug

#### Phase

Not Applicable

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

Naltrexone

# Primary outcome(s)

Effect of naltrexone compared to placebo on maximal capsaicin-induced cough frequency

#### Key secondary outcome(s))

No secondary outcome measures

#### Completion date

01/04/2013

# **Eligibility**

# Key inclusion criteria

- 1. Male
- 2. Aged 18 75 years old
- 3. Normal lung function
- 4. No current or past history of chronic cough or chronic respiratory illness
- 5. No current or past history of chronic pain, irritable bowel syndrome or chronic headaches
- 6. No current or past history of psychiatric illness
- 7. No current history of reflux disease or post-nasal drip syndrome

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

Nο

#### Age group

**Not Specified** 

#### Sex

Male

#### Key exclusion criteria

- 1. Age >75 years
- 2. Recent upper respiratory tract infection (<4weeks)
- 3. Use of ACE inhibitors
- 4. Use of centrally acting medications that may affect the cough reflex
- 5. History of drug or alcohol abuse
- 6. Current smoker or ex-smoker with >10 pack year smoking history
- 7. A previous or current history of liver disease
- 8. Dependency on opioids
- 9. Current use of opiates
- 10. Known hypersensitivity to naltrexone

#### Date of first enrolment

01/08/2012

#### Date of final enrolment

01/04/2013

# Locations

#### Countries of recruitment

United Kingdom

England

# Study participating centre

# **Wythenshawe Hospital**

Manchester United Kingdom M23 9LT

# Sponsor information

#### Organisation

South Manchester University Hospital (UK)

#### **ROR**

https://ror.org/00he80998

# Funder(s)

### Funder type

Research council

#### **Funder Name**

Medical Research Council [MRC] (UK) ref: G0900449

#### 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**

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?

Participant information sheet Participant information sheet 11/11/2025 No

Yes