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

Submission date
05/09/2012

Recruitment status
No longer recruiting

Registration date
10/09/2012

Overall study status
Completed

Last Edited
07/12/2017

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
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Contact information

Type(s)
Scientific

Contact name
Miss Danielle Yuill

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

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

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/08/2012

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

Age group
Not Specified

Sex
Male

Target number of participants
UK Sample Size: 20

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
England

United Kingdom

Study participating centre
Wythenshawe Hospital
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
South Manchester University Hospital (UK)

Sponsor details
Wythenshawe Hospital
Southmoor Road
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] (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

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