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Are macrolide antibiotics effective in chronic idiopathic cough?

Submission date
23/06/2009

Recruitment status
No longer recruiting

Registration date
23/09/2009

Overall study status
Completed

Last Edited
24/08/2016

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cough is an extremely common symptom, and usually settles by itself without any treatment. A small number of people experience a more persistent cough which lasts for more than 8 weeks. In most cases there is an underlying cause for which we currently have established treatments. For cases where there is no underlying cause, or where current treatment does not improve symptoms, there is no treatment at the moment. Several patients seen in our clinic have seen an improvement in their cough with the antibiotic azithromycin. We designed this study to test the effect of this treatment in a group of patients with persistent cough, and to see if we can identify which patients may benefit from this antibiotic.

Who can participate?
Non-smoking subjects aged 18 to 80 (either sex) with idiopathic cough for at least 2 months.

What does the study involve?
Before taking part, you will be screened to make sure there is no underlying cause for your cough, and that you have had a proper trial of appropriate treatments before taking a trial drug. If you take part in this study, you will be asked to take one tablet three times a week for 8 weeks in addition to your usual medication. At each study visit we will ask you to rate the severity of your cough, and complete a questionnaire measuring different aspects of your cough. You will also provide a breath sample to measure inflammation in the lungs, and a blood sample at each visit. The study is a placebo-controlled trial, so half of the participants will be randomly allocated to take a dummy pill which resembles the active tablet but has no active effects. Neither you nor the trial staff will be aware which treatment you are receiving for the duration of the trial, but you will be informed of your treatment allocation at the end of the trial.

What are the possible benefits and risks of participating?
The main benefits are that your cough may improve, or that you help to develop an additional treatment for patients with cough. Azithromycin is a commonly prescribed antibiotic that has been in use for many years. The main side effects that some people experience are nausea, vomiting, smell and taste disturbances, abdominal discomfort, diarrhoea and headache. Less common side effects are effects on liver blood tests, joint and muscle aches. Other side effects are rare.

Where is the study run from?
Nottingham Respiratory Biomedical Research Unit (UK)

When is the study starting and how long is it expected to run for?
July 2009 to July 2011

Who is funding the study?
Nottingham Respiratory Biomedical Research Unit (UK)

Who is the main contact?
Dr Tim Harrison
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Contact information

Type(s)
Scientific

Contact name
Dr Tim Harrison

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2

Study information

Scientific Title
Macrolide antibiotics in the treatment of chronic idiopathic cough: a randomised double-blind, placebo-controlled, parallel-group trial

Acronym
MAC

Study objectives
Macrolide antibiotics are an effective treatment in chronic idiopathic cough.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham Research Ethics Committee 2, 11/12/2008, ref: 08/H0408/121

Study design
Randomised double-blind placebo-controlled parallel-group 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 idiopathic cough

Interventions
Azithromycin 500 mg for 3 days followed by 250 mg three times weekly for 7 weeks or matching placebo treatment regimen.

Intervention Type
Drug

Phase
Phase III

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

Primary outcome measure
Leicester Cough Questionnaire score, measured after 8 weeks' treatment with azithromycin or placebo

Secondary outcome measures

1. Cough severity score
2. Adverse effects
Measured at study visits after 4 weeks, 8 weeks and 12 weeks

Overall study start date
01/07/2009

Completion date
01/07/2011

Eligibility

Key inclusion criteria
Non-smoking subjects aged 18 to 80 years (either sex) with idiopathic cough for at least 2 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Active smoking or smoking history in excess of 20 pack years
2. Non-idiopathic cough or other major co-morbidity including abnormal liver function tests
3. Medication known to interact with azithromycin

Date of first enrolment
01/07/2009

Date of final enrolment
01/07/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nottingham Respiratory Biomedical Research Unit
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
Research Innovation Services
King's Meadow Campus
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England
United Kingdom
NG7 2NR
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Sponsor type
University/education

Website
http://www.nottingham.ac.uk/

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Nottingham Respiratory Biomedical Research Unit (UK)

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?
Results article	results	01/04/2016		Yes	No
HRA research summary			28/06/2023	No	No