

Are macrolide antibiotics effective in chronic idiopathic cough?

Submission date 23/06/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/09/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/08/2016	Condition category Signs and Symptoms	<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

1. Cough severity score

2. Adverse effects

Measured at study visits after 4 weeks, 8 weeks and 12 weeks

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

80 years

Sex

All

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**

United Kingdom

England

Study participating centre

Nottingham Respiratory Biomedical Research Unit

Nottingham

United Kingdom

NG5 1PB

Sponsor information**Organisation**

University of Nottingham (UK)

ROR

https://ror.org/01ee9ar58

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Nottingham Respiratory Biomedical Research Unit (UK)

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