

# Are macrolide antibiotics effective in chronic idiopathic cough?

<b>Submission date</b> 23/06/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/09/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/08/2016	<b>Condition category</b> 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  
tim.harrison@nottingham.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Tim Harrison

**Contact details**  
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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

Nottingham

England

United Kingdom

NG7 2NR

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paul.cartledge@nottingham.ac.uk

**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?
<a href="#">Results article</a>	results	01/04/2016		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No