# The Effect of Long term Low dose Erythromycin on cough frequency in chronic unexplained cough: a randomised double-blind placebo controlled parallel group trial

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
24/07/2007		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
06/08/2007	Completed	[X] Results		
<b>Last Edited</b> 26/10/2012	<b>Condition category</b> Signs and Symptoms	[] Individual participant data		

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Nadia Yousaf

#### Contact details

Glenfield Hospital Groby Road Leicester United Kingdom LE3 9QP

# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

#### Scientific Title

## Acronym

**ELLE** 

## Study objectives

Long term low dose erythromycin will improve both objective and subjective markers of chronic unexplained cough.

# Ethics approval required

Old ethics approval format

## Ethics approval(s)

Leicestershire, Northamptonshire and Rutland Research Ethics Committee 1, 26th October 2007 (ref: 07/H0406/193).

## Study design

Randomised double-blind placebo controlled parallel group trial

## Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

Not specified

# Study type(s)

Treatment

## Participant information sheet

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

Chronic unexplained cough

### **Interventions**

250 mg of erythromycin once a day for three months or placebo once a day for three months.

## Intervention Type

Drug

#### Phase

**Not Specified** 

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

## Erythromycin

## Primary outcome measure

24-hour cough frequency.

Primary and secondary endpoints will be measured at baseline, 6 weeks into treatment, at 3 months (at the end of treatment) and at 3 months after the end of treatment.

## Secondary outcome measures

- 1. Leicester cough questionnaire score
- 2. Visual analogue score
- 3. Difference in sputum inflammatory markers

Primary and secondary endpoints will be measured at baseline, 6 weeks into treatment, at 3 months (at the end of treatment) and at 3 months after the end of treatment.

## Overall study start date

01/09/2007

## Completion date

01/08/2009

# **Eligibility**

## Key inclusion criteria

- 1. Cough lasting greater than eight weeks
- 2. Normal Spirometry
- 3. A Provocative Concentration of methacholine required to cause a 20% fall (PC20) in Forced Expiratory Volume in one second (FEV1) of greater than 8 mg/ml
- 4. A normal sputum eosinophil count (less than 3%)
- 5. No response to a three-month trial of treatment with a high dose Proton-Pump Inhibitor (PPI)
- 6. No response to a trial of a nasal steroid
- 7. A normal thoracic Computed Tomography (CT)

# Participant type(s)

**Patient** 

## Age group

**Not Specified** 

#### Sex

**Not Specified** 

# Target number of participants

40

## Key exclusion criteria

- 1. Current smokers or past smokers with a greater than 10 pack year history will be excluded
- 2. Those with a history of intolerance macrolide antibiotics
- 3. Pregnant or breastfeeding women

## Date of first enrolment

01/09/2007

## Date of final enrolment

01/08/2009

# Locations

## Countries of recruitment

England

**United Kingdom** 

# Study participating centre Glenfield Hospital

Leicester United Kingdom LE3 9QP

# Sponsor information

## Organisation

University Hospitals of Leicester NHS Trust (UK)

## Sponsor details

c/o Professor David Rowbotham Leicester General Hospital Research Office Gwendolen Road Leicester England United Kingdom LE5 4PW

## Sponsor type

Hospital/treatment centre

#### Website

http://www.uhl-tr.nhs.uk/

## **ROR**

https://ror.org/02fha3693

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Glenfield Hospital Clinical Trials 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	01/12/2010		Yes	No