

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1

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).

Primary study design

Interventional

Study design

Randomised double-blind placebo controlled parallel group trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre
Glenfield Hospital
Leicester
United Kingdom
LE3 9QP

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

ROR
<https://ror.org/02fha3693>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Glenfield Hospital Clinical Trials 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	01/12/2010		Yes	No