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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

Registration date
06/08/2007

Overall study status
Completed

Last Edited
26/10/2012

Condition category
Signs and Symptoms

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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).

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