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Macrolides in refractory asthma

Submission date 23/10/2008	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 23/01/2009	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 20/06/2016	**Condition category** Respiratory	[ ] Individual participant data [ ] Record updated in last year

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
Final version 1.1

Study information

Scientific Title
MACrolides in Refractory Asthma: a single-centre randomised placebo-controlled two-period cross-over trial

Acronym

MACRA

Study objectives
Azithromycin improves bronchial hyper-responsiveness in patients with refractory asthma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham Research Ethics Committee 2, 06/06/2008, ref: 08/H0408/64

Primary study design
Interventional

Study design
Single-centre randomised two-period cross-over placebo-controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Refractory asthma

Interventions
Azithromycin 250 mg three times a week for six weeks versus matching placebo three times a week for six weeks.

Intervention Type
Drug

Phase
Phase IV

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

Primary outcome(s)
Bronchial reactivity (the dose of methacholine producing a 20 percent fall in FEV1 [PD20 methacholine]).

Primary and secondary outcomes measured at the end of each 6 week treatment period.

Key secondary outcome(s)
1. Number of exacerbations requiring treatment with oral corticosteroids
2. Number of exacerbations requiring an increase in asthma therapy
3. Total dose of oral corticosteroids taken during the treatment period
4. Inhaled corticosteroid use
5. Reliever medication use
6. FEV1
7. Peak expiratory flow (PEF)
8. Exhaled nitric oxide

9. Blood and sputum differential cell counts
10. Asthma symptoms
11. Asthma Control Questionnaire (ACQ) score
12. Asthma Quality of Life Questionnaire (AQLQ)
13. Liver function tests
14. Adverse effects
15. Participants' views on study design, acceptability and issues that would be important to consider when designing a larger trial

Primary and secondary outcomes measured at the end of each 6 week treatment period.

Completion date
01/07/2010

Eligibility

Key inclusion criteria
1. Non-smoking subjects
2. Aged 16 to 80 years, either sex
3. Refractory asthma, forced expiratory volume in one second (FEV1) greater than 50% predicted and greater than 1L and measurable airway responsiveness to methacholine challenge

Refractory asthma will be defined as an FEV1/forced vital capacity (FVC) ratio less than 70% with evidence of poor asthma control in terms of regular night-time awakening (greater than 2/week) or more than four puffs of relief medication/day (greater than twice/week) requiring repeated (two or more per year) courses of oral corticosteroids despite treatment with high dose inhaled corticosteroids (at least 1000 µg beclomethasone or equivalent) and treatment with, or a previous unsuccessful trial of, a long-acting beta-agonist or leukotriene antagonist.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Poor compliance with usual asthma treatment
2. Pregnancy
3. Inadequate contraception or lactation
4. Active smoking or smoking history in excess of 20 pack years
5. A clinical diagnosis of allergic bronchopulmonary aspergillosis or significant bronchiectasis
6. Other major co-morbidity including abnormal liver function tests or medication known to interact with azithromycin

Date of first enrolment

01/01/2009

Date of final enrolment
01/07/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Nottingham
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
University of Nottingham (UK)

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
University/education

Funder Name
University of Nottingham (UK)

Alternative Name(s)
The University of Nottingham

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary