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Mepolizumab and exacerbation frequency in refractory eosinophilic asthma: a randomised, double blind, placebo controlled trial

Submission date
04/05/2005

Recruitment status
No longer recruiting

Registration date
10/08/2005

Overall study status
Completed

Last Edited
10/03/2009

Condition category
Respiratory

[_] 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

Protocol serial number
125770

Study information

Scientific Title

Study objectives

Mepolizumab which is a monoclonal antibody against interleukin 5, will effectively suppress eosinophilic airway inflammation and lower exacerbation frequency in severe asthmatics with evidence of persistent eosinophilic airway inflammation and a history of recurrent asthma exacerbations (greater than or equal to 2/year).

The hypothesis is based upon previous studies that have demonstrated a temporal relationship between a rise in sputum eosinophilia predicting onset of exacerbations. Steroid therapy targeted at lowering sputum eosinophil counts have been effective in lowering exacerbation frequency. Following on from this, mepolizumab has been shown in pilot studies to be effective in lowering both blood and sputum eosinophil counts and if the previous observations are robust in their hypothesis that sputum eosinophilia is causally related to asthma exacerbations, then we would expect mepoloizumab to achieve control of exacerbations through its mechanism of action. The present study has been designed to test this hypothesis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Obtained before recruitment of the first participant.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
12 month randomised double blind placebo contolled parallel group trial to receive either placebo or monoclonal antibody therapy to interleukin 5 (mepolizumab) - 750 mg intravenously over 30 minutes, monthly.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Sputum eosinophil counts measured every 3 months and exacerbation frequency over the 12 month treatment period. We have 80% power to detect a 50% change in exacerbation frequency over 1 year for a total of 60 trial participants.

Key secondary outcome(s))
1. Asthma symptoms and quality of life
2. Computed tomography (CT) and bronchial biopsy evidence of airway remodelling (i.e. structural changes to the airway wall from long standing chronic airway inflammation)

Completion date
31/07/2007

Eligibility

Key inclusion criteria
1. 60 participants meeting American thoracic criteria for refractory asthma
2. On intensive corticosteroid therapy - either oral and/or inhaled
3. A history of two or more exacerbations of asthma requiring oral corticosteroid rescue therapy in one year
4. Evidence of persistent eosinophilic inflammation in sputum - sputum eosinophils greater than 3% of total cell count

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Participants who do not meet American Thoracic Society criteria for severe asthma
2. Participants who have not demonstrated evidence of persistent eosinophilic airway inflammation (sputum eosinophil counts of greater than or equal to 3% of total cell count
3. Partcipants who are current smokers or who have a cumulative smoking history of greater than 15 pack years
4. Participants with significant co morbidity - including other symptomatic respiratory diagnoses, evidence of recurrent bacterial respiratory tract infections (greater than or equal to 2 per year), symptomatic ischaemic heart disease and mental health or other conditions that interfere with participant compliance with the study
5. Pregnant females or women of child bearing age not practising effective contraception during the study

Date of first enrolment
01/08/2005

Date of final enrolment
31/07/2007

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
Government

Funder Name
University Hospitals of Leicester NHS Trust (UK)

Funder Name
Added as of 02/01/2008:

Funder Name
GlaxoSmithKline (UK)

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type

Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/03/2009		Yes	No