# The value of measuring airway inflammation in the management of asthma

Submission date Recruitment status Prospectively registered 23/01/2004 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 23/01/2004 Completed [X] Results Individual participant data **Last Edited** Condition category 08/11/2022 Respiratory

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Christopher Brightling

#### Contact details

Glenfield Hospital Groby Road Leicester United Kingdom LE3 9QP

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers RBF 00XX2

# Study information

Scientific Title

The value of measuring airway inflammation in the management of asthma

#### **Study objectives**

Test the hypothesis that managing patients with asthma by effectively suppressing airway inflammation, using a standardised protocol, will improve the control of mild exacerbations, airway responsiveness and symptoms compared with standard clinical approach.

### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

# Study type(s)

Treatment

#### Participant information sheet

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

Asthma

#### **Interventions**

- 1. Treatment of airways inflammation
- 2. Standard care

## Intervention Type

Other

#### Phase

Not Applicable

## Primary outcome measure

Improved asthma control; control of airway inflammation; change in spirometry over one-year, severe exacerbations; total use of inhaled corticosteroids in each group; proportion of patients screened with a diagnosis of asthma without objective evidence.

# Secondary outcome measures

Not provided at time of registration

# Overall study start date

19/06/2000

# Completion date

18/05/2002

# **Eligibility**

# Key inclusion criteria

80 patients with asthma

# Participant type(s)

**Patient** 

### Age group

Adult

### Sex

Both

# Target number of participants

80

#### Total final enrolment

74

# Key exclusion criteria

Does not meet inclusion criteria

## Date of first enrolment

19/06/2000

#### Date of final enrolment

18/05/2002

# Locations

# Countries of recruitment

England

**United Kingdom** 

# Study participating centre Glenfield Hospital

Leicester United Kingdom LE3 9QP

# Sponsor information

#### Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

# Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

#### Sponsor type

Government

#### Website

http://www.doh.gov.uk

# Funder(s)

#### Funder type

Government

#### Funder Name

NHS Executive Trent (UK)

# **Results and Publications**

#### Publication and dissemination plan

Not provided at time of registration

# Intention to publish date

# Individual participant data (IPD) sharing plan

Not provided at time of registration

## IPD sharing plan summary

Not provided at time of registration

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results article30/11/2002YesNo