

# A study to assess the safety and the effects of using a growth factor, keratinocyte growth factor (KGF), in patients with moderate asthma

<b>Submission date</b> 16/06/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 07/10/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 24/05/2016	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Peter Howarth

**Contact details**  
IIR (RCMB) MP810  
Level F, South Block  
Southampton General Hospital  
Tremona Road  
Southampton  
United Kingdom  
SO16 6YD

-  
P.H.Howarth@soton.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

BRU 3.1, Sponsor no. RHM MED 0879

# Study information

## Scientific Title

Safety and efficacy of parenteral keratinocyte growth factor (KGF) in moderate asthma subjects: a double-blind placebo-controlled randomised parallel group trial

## Study objectives

That restoration of the bronchial epithelial barrier in asthma by treatment with KGF will reduce the responsiveness of the lungs to bronchoconstrictor agents, reduce airway inflammation and improve clinical disease expression.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Pending as of 17/06/2009 from the Southampton and South West Hampshire Local Research Ethics Committee (LREC)

## Study design

Randomised double blind placebo controlled parallel group trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Asthma

## Interventions

The study population will be screened including medical history, examination, spirometry, diary card monitoring, exhaled nitric oxide measurement, skinprick testing, mannitol and metacholine provocation tests and baseline bronchoscopy. The intervention group will receive intravenous keratinocyte growth factor (KGF) in a 'collapsed dose' regime, at a dose of 180 µg/kg, given as an infusion on days 0 and day 11 of the trial. The control group will receive saline infusions. In between the doses and following the second doses the subjects will have further provocation

tests and a further bronchoscopy. Subjects will be followed up for 36 days following the initial dose of the study drug/placebo.

## **Intervention Type**

Drug

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Keratinocyte growth factor

## **Primary outcome measure**

Change in provocative concentration in mannitol causing a 20% fall in FEV1 (PC20), measured in screening and on days 3, 14, 18 and 36

## **Secondary outcome measures**

1. Asthma symptoms, assessed continuously during the trial
2. Short acting B-2-agonist usage, assessed continuously during the trial
3. Lung function (home peak expiratory flow rate [PEFR] recording and clinic FEV1 and forced vital capacity [FVC])
4. Change in PC20 methacholine, assessed in screening and on day 17 and 35
5. Change in exhaled NO (eNO), assessed in screening and on days 3, 14, 18 and 36
6. Expression of ZO-1 and occludin in the bronchial epithelium
7. Bronchial biopsy epithelial integrity
8. Mucosal cellular inflammation (eosinophils, mast cells, neutrophils T-cells), assessed from bronchocopy in screening and on day 21
9. Epithelial activation markers (interleukin-8 [IL-8], regulated upon activation, normal T cell expressed and secreted [RANTES], macrophage inflammatory protein-1alpha [MIP-1a], macrophage chemotactic protein-1 [MCP-1], transforming growth factor alpha [TGF-a], epidermal growth factor receptor [EGFR]), assessed from bronchocopy in screening and on day 21
10. Safety readouts (clinical adverse event reporting), assessed continuously
11. Safety-related histochemistry readouts (epithelial Ki 61), assessed continuously

## **Overall study start date**

01/08/2009

## **Completion date**

01/11/2009

## **Eligibility**

### **Key inclusion criteria**

1. Aged 18 - 50 years, either gender
2. Confirmed diagnosis of asthma for greater than 1 year as defined by British Thoracic Society (BTS) guidelines, requiring treatment with high dose inhaled corticosteroids in combination with long acting beta-2-agonists, with persisting symptoms requiring use of short-acting beta agonist therapy greater than 3 x/week
3. Lifelong non-smoker

4. Forced expiratory volume in one second (FEV1) greater than 40%
5. Subject must understand the procedures of the study and agree to participation in the study by providing written informed consent
6. Subject considered fit enough to undergo lung function testing including provocation tests, and bronchoscopy
7. Subject must not be participating in another clinical trial or have done so within the last 12 weeks

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

50 Years

**Sex**

Both

**Target number of participants**

20

**Key exclusion criteria**

1. Pregnancy (where pregnancy is defined as the state of a female after conception and until the termination of gestation, confirmed by a positive human chorionic gonadotrophin [hCG] laboratory test greater than 5 mIU/ml), an intention to become pregnant or breast-feeding (lactating)
2. Subjects with active lung disease other than asthma
3. Significant medical (cardiopulmonary, neurological, renal, endocrine, gastrointestinal, psychiatric, hepatic or haematological) co-morbidity which in the view of the investigator could impact on the interpretation of results or participation in the trial, or which is uncontrolled with standard treatment
4. Current participation in another clinical trial or previous participation within the last 12 weeks
5. Alcohol or active drug abuse
6. Ongoing allergen desensitisation therapy
7. Regular use of sedatives, hypnotics, tranquilisers
8. Cancer or previous history of cancer
9. Inability to understand directions for dosing and study assessment
10. Inability to be contacted in case of emergency

**Date of first enrolment**

01/08/2009

**Date of final enrolment**

01/11/2009

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

IIR (RCMB) MP810

Southampton

United Kingdom

SO16 6YD

# Sponsor information

## Organisation

Southampton University Hospitals NHS Trust (UK)

## Sponsor details

Research and Development

Duthie Building (Trust) MP138

Southampton General Hospital

Tremona Road

Southampton

England

United Kingdom

SO16 6YD

+44 (0)2380 794 149

angela.jackson@suht.swest.nhs.uk

## Sponsor type

Hospital/treatment centre

## Website

<http://www.suht.nhs.uk/home.aspx>

## ROR

<https://ror.org/0485axj58>

# Funder(s)

## Funder type

Hospital/treatment centre

**Funder Name**

Southampton General Hospital (UK) - Internal funding by Biomedical Research Unit

## **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