

# Peroxisome proliferator-activated receptor gamma (PPAR-gamma): a novel therapeutic target for asthma?

<b>Submission date</b> 29/01/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/04/2017	<b>Condition category</b> Respiratory	<input type="checkbox"/> 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**  
NCT01134835

## **Secondary identifying numbers**

33100; EME 08/246/02

# **Study information**

## **Scientific Title**

Peroxisome proliferator-activated receptor gamma (PPAR-gamma): a novel therapeutic target for asthma? A randomised double-blind placebo-controlled clinical trial.

## **Study objectives**

To test the hypothesis that stimulation of peroxisome proliferator-activated receptor gamma (PPAR-gamma) receptors has a therapeutic role in the treatment of asthma.

Link to EME project website: <http://www.eme.ac.uk/projectfiles/0824602info.pdf>

Link to protocol: <http://www.eme.ac.uk/projectfiles/0824602info.pdf>

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Nottingham Research and Ethics Committee 2, 08/08/2008, ref: 08/H0408/120

## **Study design**

Randomised double-blind placebo-controlled two parallel group clinical 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 to request a patient information sheet

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

Asthma

## **Interventions**

Participants are required for a total of 18 weeks. Follow up and investigation is identical in both arms. The run-in period is 2 weeks. Participants are randomised to either active or placebo arms

for 12 weeks:

1. Pioglitazone 30 mg daily by mouth for 4 weeks then 45 mg daily for 8 weeks
2. Placebo 30 mg daily by mouth for 4 weeks then 45 mg daily for 8 weeks

The participants are followed up at weeks 4, 8 and 12. A final observation visit occurs at week 16 when the participants are no longer taking the IMP.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

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

Pioglitazone

### **Primary outcome measure**

FEV1 after 12 weeks

### **Secondary outcome measures**

Change over 12 weeks in:

1. Daily asthma symptoms
2. Mean morning and evening peak flow
3. Juniper asthma control questionnaire and asthma quality of life scores
4. Exhaled nitric oxide level
5. Bronchial hyper-responsiveness
6. Induced sputum cell counts
7. Mechanistic analysis. This includes assay of histone acetyltransferase (HAT) and histone deacetylase (HDAC) levels, PPAR-gamma activation and measurement of chemokines (eotaxin, monocyte chemoattractant protein-1 [MCP-1], IP10), growth factors (vascular endothelial growth factor [VEGF]) and effector mediators (cyst-leukotrienes, histamine and eosinophilic cationic protein).

### **Overall study start date**

01/01/2010

### **Completion date**

01/01/2012

## **Eligibility**

### **Key inclusion criteria**

1. Aged 18 - 75 years, of either sex, with a clinical diagnosis of asthma
2. Forced expiratory volume in one second (FEV1) greater than or equal to 60% predicted and an increase in forced expiratory volume in one second (FEV1) of greater than 12% following inhaled salbutamol 400 µg or peak flow variability greater than 12% during run in
3. Permitted medication, 0 - 800 µg inhaled beclomethasone dipropionate or equivalent and a short acting beta-2-agonist as required

### **Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

100

**Key exclusion criteria**

1. Inability to produce a sputum sample on induction
2. Currently smoking
3. Greater than 10 pack years smoking history
4. Treatment with leukotriene antagonists
5. Long-acting beta agonists or theophylline
6. Liver or cardiovascular disease
7. Oral steroid treatment or exacerbation within 6 weeks
8. Females who are pregnant, lactating or not using adequate contraception
9. Any contra-indication to pioglitazone (hypersensitivity to pioglitazone, cardiac failure, history of cardiac failure, hepatic impairment, diabetic ketoacidosis)
10. Oral or insulin treatment for diabetes
11. Treatment with gemfibrozol or rifampicin

**Date of first enrolment**

01/01/2010

**Date of final enrolment**

01/01/2012

**Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

University of Nottingham

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United Kingdom

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# Sponsor information

## Organisation

University of Nottingham (UK)

## Sponsor details

c/o Paul Cartledge  
Research Innovation Services  
King's Meadow Campus  
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## Sponsor type

University/education

## Website

<http://www.nottingham.ac.uk/>

## ROR

<https://ror.org/01ee9ar58>

# Funder(s)

## Funder type

Government

## Funder Name

Medical Research Council

## Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

**Funder Name**

Nottingham Respiratory Biomedical Research Unit (UK)

**Funder Name**

Efficacy and Mechanism Evaluation Programme

**Alternative Name(s)**

NIHR Efficacy and Mechanism Evaluation Programme, EME

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## 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?
<a href="#">Results article</a>	results	25/08/2016		Yes	No