

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

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

ClinicalTrials.gov (NCT)
NCT01134835

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised double-blind placebo-controlled two parallel group clinical trial

Study type(s)

Treatment

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(s)

FEV1 after 12 weeks

Key secondary outcome(s)

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).

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

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

Government

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory 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, Efficacy and Mechanism Evaluation (EME), EME

Funding Body Type

Government organisation

Funding Body Subtype

National government

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	25/08/2016		Yes	No

