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

Submission date 29/01/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/04/2010	**Overall study status** Completed	
Last Edited 11/04/2017	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Tim Harrison

Contact details
University of Nottingham
Respiratory Division
Clinical Sciences Building
Nottingham City Hospital
Nottingham
United Kingdom
NG5 1PB
+44 (0)115 823 1725
tim.harrison@nottingham.ac.uk

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

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

Primary study design
Interventional

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 chemotactic 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 diproprionate 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