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Discovery of novel biomarkers in peripheral arterial disease/metabolic syndrome

Submission date	Recruitment status	[ ] Prospectively registered
28/03/2007	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/06/2007	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/06/2017	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PADBelch07

Study information

Scientific Title
Discovery of novel biomarkers in peripheral arterial disease/metabolic syndrome

Acronym
PAD Wyeth

Study objectives
The overall objective of the research proposal is to determine the occurrence of biomarkers with proven links to future cardiovascular events in patients with Peripheral Arterial Disease (PAD) and type 2 diabetes receiving various standards of care medicines including pioglitazone.

On 21/06/2007 the target number of participants was changed from 70 to 80.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tayside Ethics Committee, 13/06/2007, ref: 07/S1401/43

Study design
Randomised double-blind placebo-controlled trial

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Type 2 diabetes and peripheral arterial disease

Interventions
In the Phase 1 section of this trial, blood and urine samples will be collected for the following analyses:
1.Transcriptional analysis
2. Other assays:
2.1. E selectin
2.2. P selectin
2.3. Endothelin
2.4. C-Reactive Protein (CRP)
2.5. Isoprostanes
2.6. Intercellular Adhesion Molecules (ICAM)

Laser Doppler imaging and iontophoresisces will also be performed, as well as measuring the flow mediated dilatation and arterial stiffness using the SphygmoCor pulse wave analysis system and Intima-Media Thickness.

In the Phase 2 section of this trial either 45 mg pioglitazone (orally) or a placebo will be given for 30 days to study its effect on vascular behaviour.

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Pioglitazone

Primary outcome(s)
Development of new biomarkers

Key secondary outcome(s))
Correlate clinical parameters (e.g. walking distances) in patients with PAD and type 2 diabetes treated with various standard of care medicines to genes and protein profiling in muscle biopsies.

Completion date
30/06/2008

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
For Phase 1 study subjects with PAD and type 2 diabetes will be included. PAD will be defined as patients with classical symptoms of intermittent claudication plus an Ankle brachial Blood Pressure Index (ABPI) of <0.9, the accepted cut off level for such a diagnosis.

For Phase 2 study patients with short distance claudication (<200 yards) will be selected for the walking study, as their walking distances are more reproducible (i.e. using the standardized Gardner walking treadmill protocol no more than 25% variation from 2 consecutive treadmill tests performed at least a week apart during the screening period). Patients for this second study will be type 2 diabetic patients not receiving insulin.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
1. Contraindication to thiazolidinedione group of drugs
2. Subjects taking sulphonylureas
3. Subjects with cardiovascular disease event within last three months (such as Myocardial

Infarction [MI], unstable angina and stroke)
4. For Phase 2 study, subjects having more than 25% variation from 2 consecutive treadmill tests performed at least a week apart

Date of first enrolment
01/04/2007

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
The Institute of Cardiovascular Research
Dundee
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DD1 9SY

Sponsor information

Organisation
University of Dundee (UK)

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Industry

Funder Name
Wyeth Pharmaceuticals (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration