

Discovery of novel biomarkers in peripheral arterial disease/metabolic syndrome

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| Submission date 28/03/2007 | Recruitment status Stopped | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 19/06/2007 | Overall study status Stopped | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 21/06/2017 | Condition category Nutritional, Metabolic, Endocrine | <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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

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

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 iontophoresis 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 measure

Development of new biomarkers

Secondary outcome measures

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.

Overall study start date

01/04/2007

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

Age group

Not Specified

Sex

Both

Target number of participants

80

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**

Scotland

United Kingdom

Study participating centre

The Institute of Cardiovascular Research

Dundee

United Kingdom

DD1 9SY

Sponsor information**Organisation**

University of Dundee (UK)

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/03h2bxq36>

Funder(s)

Funder type

Industry

Funder Name

Wyeth Pharmaceuticals (UK)

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