

# Discovery of novel biomarkers in peripheral arterial disease/metabolic syndrome

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

**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 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(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

United Kingdom

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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes