

# Vitamin D After Myocardial Infarction (MI): the DAMI study

<b>Submission date</b> 05/01/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/01/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/02/2018	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Small studies have shown that vitamin D, a hormone that the skin usually makes using sunshine, may be able to reduce blood pressure in some people. The majority of people in Scotland have low levels of vitamin D, and people with low vitamin D have a higher chance of a heart attack. People who have had a heart attack have blood vessels that do not work as well as normal, and this leads to a higher risk of future heart problems.

The aim of this study is to find out if giving extra vitamin D to people who have had a heart attack helps to improve the function of blood vessels. It also aims to investigate whether giving vitamin D can reduce blood pressure and cholesterol in people who have had a heart attack.

### Who can participate?

Adults >18 years who have had a heart attack

### What does the study involve?

The study lasts for six months. Participants are randomly allocated to one of two groups, and given either a teaspoon of the vitamin D oil or a placebo (dummy) oil at the start of the study, two months later, and two months after that.

The participants are seen at the start, and at 2, 4 and 6 months later. Each visit will last an hour to 1 1/2 hours. At each visit, they will receive some or all of the following depending on which visit it is:

- Blood pressure taken
- Blood sample taken
- Heart tracing (ECG)
- The function of the arteries in the fingers is measured. The participant lies down and has a thimble-like device attached to one finger on each hand. This measures blood flow in the fingertips. After 5 minutes, a blood pressure cuff is inflated on one arm and kept blown up for 5 minutes. After this, the cuff is let down and the blood flow in the fingertips is measured for another 5 minutes. No needles are used in this test.

### What are the possible benefits and risks of participating?

Although this dose of vitamin D has been used before and is known to be safe there is a small possibility of side effects. The participant is closely monitored for side effects caused by high

calcium levels: sickness, diarrhoea, thirst or dizziness. To reduce the chance of vitamin D increasing the calcium levels in their blood, they are asked not to take vitamin D supplements or calcium supplements whilst taking part in this study. Having blood taken can cause some bruising. The blood pressure cuff causes mild discomfort to some people.

Where is the study run from?  
Ninewells Hospital Dundee (UK)

When is the study starting and how long is it expected to run for?  
September 2008 to August 2011

Who is funding the study?  
Chest Heart and Stroke Scotland (UK)

Who is the main contact?  
Dr Miles Witham (Scientific)  
m.witham@dundee.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Miles Witham

**Contact details**  
Section of Ageing and Health  
Ninewells Hospital  
Dundee  
United Kingdom  
DD1 9SY  
+44 (0)1382 632436  
m.witham@dundee.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
2008CV05

## Study information

**Scientific Title**

Effects of vitamin D supplementation on markers of vascular function after myocardial infarction: a placebo controlled, double blind, parallel group, randomised controlled trial

## **Acronym**

DAMI

## **Study objectives**

Vitamin D3 supplementation will lead to improvements in vascular function, and reduce markers of thrombosis, inflammation and platelet activation that are known to be deranged in the period following myocardial infarction and that are thought to contribute to the high risk of further vascular events.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Fife and Forth Valley Research Ethics Committee, 24/06/2009, ref: 09/S0501/53

## **Study design**

Placebo-controlled double-blind parallel group randomised controlled trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **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**

Myocardial infarction

## **Interventions**

100,000 units of oral vitamin D or placebo at 0, 2 and 4 months. Total follow up is 6 months per patient.

## **Intervention Type**

Supplement

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Vitamin D

## **Primary outcome measure**

Current primary outcome measure (as of 21/02/2018):

Change in endothelial function measured using the EndoPAT finger plethysmography system between baseline and 6 months

Previous primary outcome measure:

Change in endothelial function between baseline and 6 months.

## **Secondary outcome measures**

Current secondary outcome measures (as of 21/02/2018):

1. Change in blood pressure measured using OMRON HEP 705 oscillometric automated machine at 2 and 6 months
2. Change in endothelial function measured using the EndoPAT finger plethysmography system at 2 months
3. Changes in blood markers (tumour necrotising factor (TNF) alpha, brain natriuretic peptide (BNP), high sensitivity C-reactive protein (hsCRP), von Willebrand factor, E-selectin and thrombomodulin) measured using ELISA kits at 2 and 6 months
4. QT interval and dispersion measured using a 12 lead ECG at 2 and 6 months

Previous secondary outcome measures:

1. Change in blood pressure at 2 and 6 months
2. Change in endothelial function at 2 months
3. Changes in tumour necrotising factor (TNF) alpha, brain natriuretic peptide (BNP), high sensitivity C-reactive protein (hsCRP), QT interval and dispersion, von Willebrand factor, E-selectin and thrombomodulin at 2 and 6 months

## **Overall study start date**

30/09/2008

## **Completion date**

04/08/2011

# **Eligibility**

## **Key inclusion criteria**

1. Confirmed diagnosis of myocardial infarction, based on the recently published Universal criteria for diagnosis of myocardial infarction: Troponin T greater than 0.02 plus one of the following:
  - 1.1. Symptoms consistent with myocardial ischaemia
  - 1.2. Electrocardiogram (ECG) changes consistent with myocardial ischaemia
  - 1.3. New Q waves on ECG
  - 1.4. New regional wall motion abnormality or evidence of new loss of viable myocardium on imaging
2. Admitted to Tayside Hospitals within 1 week of index event
3. Aged greater than 18 years, either sex
4. Minimum of 6 weeks after index event (to allow for medication stabilisation and percutaneous /surgical interventions)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

80

**Key exclusion criteria**

1. Estimated glomerular filtration rate (GFR) less than 40 ml/min (using the MDRD4 method)
2. Adjusted serum calcium less than 2.15 mmol/L or greater than 2.60 mmol/L
3. Liver function tests (LFTs) greater than 3 x upper limit of normal
4. Already taking vitamin D supplements. Consumption of fish oils will not be a contraindication to enrolment as the vitamin D content is very low relative to the dose used in the study.
5. Known metastatic malignancy
6. History of renal calculi or sarcoidosis
7. Supine systolic blood pressure (BP) less than 80 mmHg
8. Pregnant, lactating, or of childbearing age and not taking reliable contraception
9. Unable to give written informed consent

**Date of first enrolment**

01/10/2009

**Date of final enrolment**

31/08/2010

**Locations****Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**

**Section of Ageing and Health**

Dundee

United Kingdom

DD1 9SY

**Sponsor information**

**Organisation**

University of Dundee (UK)

**Sponsor details**

Research and Innovation Services

11 Perth Road

Dundee

Scotland

United Kingdom

DD1 4HN

-

j.z.houston@dundee.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.dundee.ac.uk/>

**ROR**

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

**Funder(s)****Funder type**

Charity

**Funder Name**

Chest, Heart and Stroke Scotland (UK) (ref: Res09/A122)

**Results and Publications****Publication and dissemination plan**

The protocol is available from the authors on request but is not available online.

**Intention to publish date****Individual participant data (IPD) sharing plan**

Study data are available for non-commercial, bona-fide academic analyses in collaboration with the authors; decisions on data access will be made between the investigators and the Sponsor (University of Dundee). Participant consent for unrestricted sharing of individual participant data was not obtained. Contact for data sharing: Dr Catrina Forde (c.forde@dundee.ac.uk)

## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	10/08/2013		Yes	No
<a href="#">Basic results</a>		14/02/2018	21/02/2018	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No