ISRCTN32927244 https://doi.org/10.1186/ISRCTN32927244

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

Submission date	Recruitment status	[X] Prospectively registered
05/01/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/01/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/02/2018	Circulatory System	

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)
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Contact information

Type(s)
Scientific

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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
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Sponsor type
University/education

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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?
Results article	results	10/08/2013		Yes	No
Basic results		14/02/2018	21/02/2018	No	No
HRA research summary			28/06/2023	No	No