# The TASCFORCE Project: Tayside Screening For risk of Cardiac Events

| Submission date 02/04/2007          | <b>Recruitment status</b><br>No longer recruiting | <ul><li>Prospectively registered</li><li>Protocol</li></ul>           |
|-------------------------------------|---|---|
| <b>Registration date</b> 05/06/2007 | <b>Overall study status</b><br>Completed          | <ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul> |
| Last Edited<br>12/02/2025           | <b>Condition category</b><br>Circulatory System   | Individual participant data   |

# Plain English summary of protocol

Background and study aims

Cardiovascular disease (heart attacks, strokes and peripheral vascular disease) remains the leading cause of death and disability in Western societies despite advances in how we treat these conditions. Preventing them from developing is better than treating them once they have presented themselves. Medical treatment, including with statins, is known to reduce the risk of cardiovascular events but drugs also have a cost both financially and in terms of side effects. Therefore it is best to target their use in people who are most likely to benefit. Currently doctors in the United Kingdom use tools based on observational studies to estimate an individual's risk of developing cardiovascular disease. This is then used to decide who to recommend preventative medication to. However, these tools are not accurate: many people estimated to be at low risk and therefore not offered treatment develop cardiovascular disease. In hindsight these people may benefit from treatment if they could be accurately identified as being at increased risk. This study is investigating the ability of a new screening programme involving blood tests and a magnetic resonance imaging (MRI) scan to identify people at increased risk of cardiovascular disease.

#### Who can participate?

Men and women in Tayside, Scotland, aged 40 years or older, free from cardiovascular disease (e. g., heart attacks, strokes, angina) and without an indication for preventative medication (e.g., statins) under current clinical guidelines.

#### What does the study involve?

Participants are assessed for their current estimated risk by taking a clinical and family history, measurement of blood pressure, weight, height, and smoking, dietary and exercise habits. Blood is taken to determine blood cholesterol and glucose levels. Blood is also analysed to check the level of B-type natriuretic peptide (BNP). Increased levels of this substance indicate that there may be some stress on the heart or vascular system. If participants are found to have a higher than average level of BNP (which may still be 'normal') they are invited to attend for an MRI scan at the Clinical Research Centre at the University of Dundee at Ninewells Hospital. This involves a scan of the heart and arteries throughout the body to look for an increased size of the heart or narrowing of the arteries. The scan involves the injection of a 'contrast' liquid into a vein to make the pictures clearer. All participants (whether they are invited for a scan or not) are followed up

by their computerised health records to see if they develop cardiovascular events or disease such as heart attacks, strokes, angina and peripheral arterial disease, as well as other outcomes such as death and prescriptions of relevant medication. The study does not involve giving any medication; however, if during assessment for the study a participant is found to have a reason to start medication as advised by current guidelines that individual and their General Practitioner (GP) will be advised of this recommendation.

What are the possible benefits and risks of participating?

Potential benefits from taking part include possible identification of previously unrecognised risk factors for cardiovascular disease. This will lead to advice to address these risk factors with medication if required. Taking part in the study will help further doctors' understanding of cardiovascular disease and may help develop future screening programmes to identify people at risk of cardiovascular disease. This has the potential to improve how we target preventative medication and could save lives. The MRI scan involves injecting a contrast liquid into a vein. A small number of people may have an allergic reaction to this which could range from a brief local reaction (itch and rash) to a more severe reaction. If this unlikely event occurs medical staff will be available to treat it. A small number of participants may have previously undiagnosed disease, such as cancers, that may be picked up incidentally during the MRI scan.

Where is the study run from?

The study is being run from the University of Dundee at Ninewells Hospital and Medical School.

When is the study starting and how long is it expected to run for? The first participant will be recruited in November and we aim to complete recruitment of 5000 volunteers by January 2013. Follow up by looking at computerised health records will be initially 2 years after the participant joins the study and then at 5 and 10 years.

## Who is funding the study?

The study is being funded by a grant from the Souter Charitable Trust, and Chest, Heart and Stroke Scotland.

Who is the main contact?

Dr Roberta Littleford, TASCFORCE Trial Manager, Division of Cardiovascular and Diabetes Medicine, Medical Research Institute, University of Dundee, Ninewells Hospital and Medical School, Dundee. DD1 9SY.

# **Contact information**

**Type(s)** Scientific

**Contact name** Prof Jill Belch

## Contact details

The Institute of Cardiovascular Research Vascular and Inflammatory Diseases Research Unit Ninewells Hospital and Medical School Dundee United Kingdom DD1 9SY +44 (0)1382 383092 j.j.f.belch@dundee.ac.uk

# Additional identifiers

**EudraCT/CTIS number** 2007-002010-19

**IRAS number** 

ClinicalTrials.gov number

**Secondary identifying numbers** Protocol no.: TASC07; MHRA: 020807

# Study information

**Scientific Title** The TASCFORCE Project: Tayside Screening For risk of Cardiac Events

# Acronym

TASCFORCE

#### **Study objectives**

Current hypothesis as of 09/01/2014:

That screening an at-risk population by magnetic resonance imaging for early signs of cardiovascular disease as measured by left ventricular mass and whole body atheroma burden will predict future cardiovascular events.

Previous hypothesis:

That screening an at-risk population by magnetic resonance imaging for early signs of heart disease as measured by left ventricular mass combined with a statin intervention in the high risk group will prevent heart attack stroke and the associated mortality.

On 09/01/2014 the following changes were also made to the trial record:

1. The public title was changed from 'The TASCFORCE Project: Tayside Screening For risk of Cardiac Events and the effect of statin on risk reduction' to 'The TASCFORCE Project: Tayside Screening For risk of Cardiac Events'

2. The study design was changed from 'Double-blind randomised placebo-controlled trial' to 'Prospective normal volunteer cardiovascular risk screening study'

On 28/02/2014 the overall trial end date was changed from 01/06/2007 to 01/02/2023.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Tayside Committee on Medical Research Ethics B,13/07/2007, ref: 07/S1402/42 Added 09/01/2014: Current protocol with amendments approved 26/09/2011

# Study design

Prospective normal volunteer cardiovascular risk screening study

**Primary study design** Observational

## Secondary study design

**Study setting(s)** Hospital

Study type(s) Screening

#### Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

## Health condition(s) or problem(s) studied

Prevention of cardiovascular events in at-risk population

#### Interventions

Current interventions as of 27/02/2014: All participants will receive lifestyle counselling and leaflets on modifiable risk factors.

The baseline observations are: height, weight, BMI, total cholesterol, HDL, LDL, triglycerides, glucose, BP, heart rate, B-type natriuretic peptide (BNP), ECG, smoking history, family history of cardiovascular disease.

For those with an elevated BNP: a whole-body contrast-enhanced MRI scan. This will be used to determine left ventricular mass, whole body atheroma burden and presence of myocardial delayed enhancement to indicate cardiac ischaemia.

Follow up (for all participants) via record linkage will be for mortality, hospital admissions (with diagnosis), new diagnoses of cardiovascular disease, prescribing data. This will initially be at 2 years after recruitment and will continue for up to 10 years.

#### Previous interventions:

Simvastatin 40 mg daily versus placebo for 18 months to 2 years, and then all participants will receive life style counselling and leaflets on modifiable risk factors at one 15-minute session.

**Intervention Type** Drug

**Phase** Not Applicable

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

#### Primary outcome measure

Current primary outcome measures as of 09/01/2014: Ability of increased left ventricular mass as detected by MRI scan to predict future cardiovascular events

Previous primary outcome measures: Left ventricular mass at two years

## Secondary outcome measures

Current secondary outcome measures as of 09/01/2014: 1. Ability of BNP level to predict future cardiovascular events 2. Ability of MRI-derived whole body atheroma burden to predict future cardiovascular events

Previous secondary outcome measures: Validation of the magnetic resonance imaging (MRI) screening tool as a predictor of cardiovascular disease

# Overall study start date

01/06/2007

Completion date 01/02/2025

# Eligibility

**Key inclusion criteria** Men and women aged 40 years and over

**Participant type(s)** Patient

**Age group** Adult

**Lower age limit** 40 Years

**Sex** Both

**Target number of participants** 5000

**Total final enrolment** 4423

## Key exclusion criteria

1. Known atherosclerotic disease

- 2. Indication for statin therapy according to current clinical practice
- 3. Known primary muscle disease
- 4. Contraindication to statin

- 5. Any serious illness that may compromise the subjects safety or completion of study
- 6. Any illness which means that the subject is unable to give informed consent
- 7. Known alcohol abuse
- 8. Drinking more than two glasses of grapefruit juice per day
- 9. Pregnancy and not using reliable method of contraception

Date of first enrolment 01/06/2007

Date of final enrolment 01/01/2013

# 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**

c/o Mr James Houston Research and Innovation Services University of Dundee 11 Perth Road Dundee Scotland United Kingdom DD1 4HN +44 (0)1382 384664 j.z.houston@dundee.ac.uk

Sponsor type

University/education

# https://ror.org/03h2bxq36

# Funder(s)

**Funder type** Charity

**Funder Name** Chest, Heart and Stroke Scotland (UK)

**Funder Name** Added 28/02/2014: Souter Charitable Trust (UK)

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

#### Intention to publish date

# Individual participant data (IPD) sharing plan

Not provided at time of registration

#### IPD sharing plan summary

Not provided at time of registration

## Study outputs

| Output<br>type                       | Details  | Date<br>created | Date<br>added  | Peer<br>reviewed? | Patient-<br>facing? |
|--------------------------------------|--|-----------------|----------------|-------------------|---------------------|
| <u>Interim</u><br>results<br>article | MRI of left ventricle results  | 01/11<br>/2016  | 15/02<br>/2021 | Yes               | No                  |
| <u>Interim</u><br>results<br>article | asymptomatic atherosclerosis burden results  | 01/06<br>/2018  | 15/02<br>/2021 | Yes               | No                  |
| <u>Interim</u><br>results<br>article | Findings to date   | 21/10<br>/2022  | 24/10<br>/2022 | Yes               | No                  |
| <u>Interim</u><br>results<br>article | Prevalence of unrecognized myocardial infarction in a low-intermediate risk asymptomatic cohort and its relation to systemic atherosclerosis | 01/06<br>/2017  | 21/02<br>/2023 | Yes               | No                  |
| <u>Interim</u><br>results<br>article | Systemic arteriosclerosis is associated with left ventricular remodeling but not atherosclerosis   | 30/01<br>/2018  | 21/02<br>/2023 | Yes               | No                  |

| <u>Interim</u><br>results<br>article | Whole-body cardiovascular MRI for the comparison of atherosclerotic<br>burden and cardiac remodelling in healthy South Asian and European<br>adults | 15/06<br>/2016 | 21/02<br>/2023 Yes | No |
|--------------------------------------|---|----------------|--------------------|----|
| <u>Results</u><br>article            | Median follow-up of 10 years for was performed cardiovascular events using national electronic health records                                       | 05/11<br>/2025 | 12/02<br>/2025 Yes | No |
| <u>Results</u><br>article            | Median follow-up of 10 years for was performed cardiovascular events using national electronic health records                                       | 05/11<br>/2025 | 12/02<br>/2025 Yes | No |