ISRCTN38976321 https://doi.org/10.1186/ISRCTN38976321

The TASCFORCE Project: Tayside Screening For risk of Cardiac Events

Submission date	Recruitment status	[_] Prospectively registered
02/04/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/06/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/02/2025	Circulatory System	

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

Clinical Trials Information System (CTIS)
2007-002010-19

Protocol serial number
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

Study type(s)
Screening

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(s)
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

Key secondary outcome(s))
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

Completion date
01/02/2025

Eligibility

Key inclusion criteria
Men and women aged 40 years and over

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Sex
All

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
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
Charity

Funder Name
Chest, Heart and Stroke Scotland (UK)

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

Results and Publications

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 type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Median follow-up of 10 years for was performed cardiovascular events using national electronic health records	05/11/2025	12/02/2025	Yes	No
Results article	Median follow-up of 10 years for was performed cardiovascular events using national electronic health records	05/11/2025	12/02/2025	Yes	No
Interim results article	MRI of left ventricle results	01/11/2016	15/02/2021	Yes	No
Interim results article	asymptomatic atherosclerosis burden results	01/06/2018	15/02/2021	Yes	No
Interim results article	Findings to date	21/10/2022	24/10/2022	Yes	No
Interim results article	Prevalence of unrecognized myocardial infarction in a low-intermediate risk asymptomatic cohort and its relation to systemic atherosclerosis	01/06/2017	21/02/2023	Yes	No
Interim results article	Systemic arteriosclerosis is associated with left ventricular remodeling but not atherosclerosis	30/01/2018	21/02/2023	Yes	No
Interim results article	Whole-body cardiovascular MRI for the comparison of atherosclerotic burden and cardiac remodelling in healthy South Asian and European adults	15/06/2016	21/02/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes