ISRCTN12157806 https://doi.org/10.1186/ISRCTN12157806

The Danish Cardiovascular Screening Trial (DANCAVAS)

Submission date	Recruitment status	[_] Prospectively registered
11/03/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
21/03/2015	Ongoing	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/05/2024	Circulatory System	

Plain English summary of protocol

Background and study aims
The significant increase in the average lifespan has resulted in an increase in medical and community resources needed to manage serious age-related diseases, such as cancer and cardiovascular disease (for example, heart disease and stroke). Routine medical checks by general practitioners are often not sufficient to identify a person developing cardiovascular disease. In this study, we aim to
investigate whether advanced cardiovascular screenings will prevent cardiovascular events (such as a heart attack) , and whether the possible health benefits are cost effective.

Who can participate?
Danish men aged between 65-74 years living in the Island of Fyn, and the communities of Vejle and Silkeborg in Denmark

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are invited to attend an advanced cardiovascular screening examination. The screening includes detecting coronary artery disease and aneurysms (via the use of CT scans), blood pressure tests, tests to check heart rhythm and tests to check for high cholesterol levels and diabetes. Biological samples will be performed for biomarker and translational research. Participants in group 2 (control) receive their usual medical care and are not offered an advanced cardiovascular screening examination.

What are the possible benefits and risks of participating?
For participants in group 1 found to be developing cardiovascular disease, preventive actions, including medical treatment and possibly surgery, will be taken.

Where is the study run from?
Four hospital sites in the Island of Fyn, Vejle and Silkeborg (Denmark)

When is the study starting and how long is it expected to run for?
January 2014 to January 2026

Who is funding the study?
Region of Southern Denmark Research Group

Who is the main contact?
Professor Jes Lindholt

Contact information

Type(s)
Public

Contact name
Dr Jes Lindholt

Contact details
Department of Cardiothoracic and Vascular Surgery T
Odense
Denmark
5000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT03946410

Secondary identifying numbers
N/A

Study information

Scientific Title
The Danish Cardiovascular Screening Trial (DANCAVAS): a large population-based randomized clinical multicenter trial testing combo cardiovascular screening in men aged 65-74 years

Acronym
DANCAVAS

Study objectives
The primary hypothesis is that the offer of an extensive circulatory screening and intervention programme fulfills the WHO criteria for screening especially concerning the significance of the diseases, the treatment benefits, and the cost effectiveness.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Southern Denmark Region Committee on Biomedical Research Ethics (S-20140028) and the Data Protection Agency

Study design
Randomized, clinical controlled, interventional multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
Half of the study participants are randomised to the usual care without any screening (control group), while the other half of participants are invited to a screening and intervention programme that measures traditional risk factors, CAC, aneurysms, and PAD (screening group) and offer general cardiovascular prevention in case of positive finding.

Intervention Type
Mixed

Primary outcome measure
All cause mortality

Secondary outcome measures
1. Costs and cost effectiveness after 3, 5 and 10 years to assess possible health and/or societal benefits of the screening.
2. Nationwide registry based information on health care consumption including contacts to GP and use of drugs, as well as hospital submissions.

Overall study start date
01/01/2014

Completion date
01/01/2026

Eligibility

Key inclusion criteria

Danish men aged 65-74 years old living in the Island of Fyn, and the communities of Vejle and Silkeborg in Denmark.

Participant type(s)
All

Age group
Senior

Lower age limit
65 Years

Upper age limit
74 Years

Sex
Male

Target number of participants
45000

Total final enrolment
47322

Key exclusion criteria
1. Women
2. Men younger than 65 years

Date of first enrolment
01/10/2014

Date of final enrolment
01/05/2017

Locations

Countries of recruitment
Denmark

Study participating centre
Odense University Hospital
Sdr. Boulevard 29
5000 Odense C
Denmark
5000

Study participating centre

Vejle Sygehus
Kabbeltoft 25
Vejle
Denmark
7100

Study participating centre
Regionshospitalet Silkeborg
Falkevej 3
Silkeborg
Denmark
8600

Sponsor information

Organisation
The Region of Southern Denmark

Sponsor details
Damhaven 12
Vejle
Denmark
7100

Sponsor type
Government

ROR
https://ror.org/0290a6k23

Funder(s)

Funder type
Not defined

Funder Name
Region of Southern Denmark Research Group (Region Syddanmarks Forskningspulje (Denmark))

Results and Publications

Publication and dissemination plan
The entire study population, the controls as well as the screening group, will be monitored for a period of 10 years. The primary efficiency variable is overall mortality, while hospitalisations and deaths from cardiovascular diseases (cerebrovascular, cardiac, aneurysm, or other vascular) are the secondary variables. These endpoints are compared for the two groups using a Cox proportional hazards-regression analysis. The cost-efficiency calculation will be adjusted for the quality of life.
An independent endpoint committee will review registry data on the causes of death and data from the Danish National Patient Register concerning hospital admissions; supplemental data will be requested from hospitals and the GP if needed. The health economics of the screening program will be evaluated with two types of analyses. A trial-based evaluation will be conducted after 5 and 10 years of follow-up, whereas the lifetime perspective on the health economics of the screening will be evaluated in a separate decision analytic model for the men and women.
First major publication date is planned for 1st of July 2018

Intention to publish date
01/07/2018

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/12/2015		Yes	No
Results article	results	01/04/2020	06/11/2019	Yes	No
Results article	results	23/01/2020	12/03/2020	Yes	No
Results article	baseline results	27/03/2019	12/08/2021	Yes	No
Results article	results	10/08/2021	12/08/2021	Yes	No
Statistical Analysis Plan	version 6.0	03/01/2022	04/01/2022	No	No
Results article	5-year follow-up	27/08/2022	30/08/2022	Yes	No
Results article	5 year outcomes	13/10/2022	17/01/2023	Yes	No
Statistical Analysis Plan	version 7	17/01/2023	17/01/2023	No	No
Other publications	Post hoc analyses	13/05/2024	14/05/2024	Yes	No