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
21/01/2026	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 2027

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

ClinicalTrials.gov (NCT)
NCT03946410

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

Study type(s)
Screening

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(s)
All cause mortality

Key secondary outcome(s))
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.

Completion date
01/01/2027

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

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Upper age limit
74 years

Sex
Male

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

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

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?
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
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
Protocol article	protocol	05/12/2015		Yes	No
Other publications	Post hoc analyses	13/05/2024	14/05/2024	Yes	No
Statistical Analysis Plan	version 6.0	03/01/2022	04/01/2022	No	No
Statistical Analysis Plan	version 7	17/01/2023	17/01/2023	No	No