SCreening adults with Obesity to Reduce Heart Failure Events

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To investigate whether active screening for early signs of HF and its risk factors in adults with obesity without known heart disease improves clinical outcome.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56190

Source
ToetsingOnline

Brief title
SCOR(hf)E

Condition

- Other condition
- Heart failures

Synonym
heaviness, severe overweight

Health condition

obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Cardiologie
Source(s) of monetary or material Support: Biotronik,Boehringer Ingelheim,Sanofi BV,Subsidie van Stichting BOF (Bevordering Onderzoek Franciscus)

Intervention

Keyword: Heart failure, Obesity, Screening

Outcome measures

Primary outcome

The main study endpoint is a combined endpoint of left ventricular dysfunction

and/or HF admission.

Secondary outcome

- Prevalence at baseline of not yet diagnosed HF as identified by active

screening

- Prevalence at baseline of undiscovered risk factors for HF (e.g.

hypertension, diabetes) as identified by active screening

- Risk factors for having HF in subjects with a HF diagnosis at baseline by

active screening (e.g. age, sex, BMI, waist circumference, hypertension,

diabetes)

- Quality of life (EQ-5D-5L questionnaire) at 1 year follow-up in all subjects

- Effect of HF treatment on dyspnea (NYHA classification) at 1 year follow-up

in screened patients with HF at the time of screening

Study description

Background summary

Obesity prevalence in Dutch adults increased to 14.2% in 2020. Obesity is strongly associated with cardiovascular disease, especially heart failure (HF). HF is a serious condition with significant morbidity and mortality. HF in people with obesity often remains undetected for a relatively long time, because symptoms are attributed to the obesity and not to possible HF. As a result, individuals seek help late for already advanced HF. Screening may reveal HF risk factors or a HF diagnosis. Early treatment initiation will improve prognosis, both in terms of quality of life and morbidity and mortality.

Study objective

To investigate whether active screening for early signs of HF and its risk factors in adults with obesity without known heart disease improves clinical outcome.

Study design

Investigator driven, not blinded, randomized controlled superiority trial.

Intervention

Participants will be randomized to either an active screening on HF and its risk factors (the intervention group) or standard care. The intervention group will be screened using anamnesis, physical examination, an electrocardiogram, blood tests and an echocardiogram. In a subset of patients in the intervention group, screening will reveal HF or additional HF risk factors, such as hypertension or diabetes, that will be treated and followed according to guidelines. Participants randomized to standard care will not undergo any tests at baseline.

Study burden and risks

The burden for participants is relatively low. Nevertheless, participants in the intervention group do have to undergo some extra tests at baseline and follow-up, and participants in the usual care group at follow-up. However, the diagnostic procedures of the study protocol are widely accepted and well-known to be free of any risk of serious adverse events. As obesity is one of the most important public health problems in the Western world and the prevalence of HF is increasing, the risk to and burden for the participants will be in proportion to the potential value of the research.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Age >=45 year, BMI >=30 kg/m2, and written informed consent.

Exclusion criteria

Known cardiac disease (determined by assessment of the available patient files and by asking the patient).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-03-2024
Enrollment:	420
Type:	Actual

Ethics review

Approved WMO Date:	20-12-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	22-02-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL84213.100.23