# Atrial Fibrillation detection in OBESity using E-health

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

# **Summary**

# ID

NL-OMON25241

**Source** Nationaal Trial Register

Brief title AF OBESE

#### **Health condition**

Obesity Atrial fibrillation (AF) Cardiac dysfunction

### **Sponsors and support**

Primary sponsor: None Source(s) of monetary or material Support: Stichting Bevordering Onderzoek Franciscus

### Intervention

### **Outcome measures**

#### **Primary outcome**

The proportion of obesity patients with AF as detected by 1 week heart rhythm registration with an AF-detection patch (before bariatric surgery). By accepted convention, an AF episode lasting at least 30 seconds is diagnostic

#### Secondary outcome

1) The proportion of obesity patients with an increased CHA2DS2VASc-score with AF as detected by an ILR during 3 months monitoring before bariatric surgery.

2) Change in the proportion of obesity patients with any AF episode as detected by an AFdetection patch between study onset (1 week monitoring before surgery) and one year after surgery (1 week monitoring).

3) Change in the proportion of obesity patients with any AF episode as detected by an ILR between study onset (3 months monitoring before surgery) and in the period of 9 to 12 months after surgery (3 months monitoring).

# **Study description**

#### **Background summary**

Rationale: Obesity is a global epidemic. Obesity is associated with an increased risk of atrial fibrillation (AF). AF is the most common sustained cardiac rhythm disorder in humans with potentially life threatening complications. Detection of subclinical AF in obesity patients would allow initiation of proper therapy and follow-up. However, to financially and logistically permit screening of subjects on AF, subjects with the highest risk of having AF should be identified. Currently, knowledge on the mechanisms through which obesity increases the risk of AF remain largely unclear and insufficient to develop such strategies. Franciscus Gasthuis & Vlietland is one of the largest bariatric surgery centers of The Netherlands, with multiple research projects focusing on the obesity patient.

Objective: To assess the prevalence of subclinical AF in obesity patients by using different contemporary AF-detection applications (primary objective). To identify high-risk criteria for an obesity patient to have AF (secondary objective). To gain insight in the pathophysiology of the relation between obesity and AF (secondary objective).

Study design: The value of AF-screening using an AF-detection patch or an insertable loop recorder (ILR) will be studied in an investigator driven, cross sectional, observational cohort study of obesity patients (primary objective). Selected patients are obesity patients who are screened for bariatric surgery, aged 50 years and older, without a history of cardiac disease. Patients will undergo conventional and advanced echocardiography and laboratory tests as well to investigate signs of subclinical cardiac dysfunction that may be related to AF (secondary objective). Also, a prospective follow-up study of obesity patients undergoing bariatric surgery will be performed to gain insight in the pathophysiology of increased risk of AF in obesity (secondary objective).

Study population: 200 consecutive adult obesity patients undergoing bariatric surgery. Main study parameters/endpoints: The main study parameter is the proportion of obesity patients with AF as detected by 1 week heart rhythm registration with an AF-detection patch (before bariatric surgery).

#### **Study objective**

There is a high prevalence of silent AF in obesity patients, which may be revealed by 1 week monitoring with a specially designed AF detection patch.

Investigation of obesity patients before and one year after bariatric surgery will help to gain insight in the underlying pathophysiology of increased risk of AF in obesity.

#### Study design

Investigation of obesity patients before and one year after bariatric surgery

#### Intervention

None

# Contacts

#### Public

Franciscus Gasthuis & Vlietland Bas van Dalen

0104616139 Scientific Franciscus Gasthuis & Vlietland Bas van Dalen

0104616139

# **Eligibility criteria**

# **Inclusion criteria**

- BMI of  $\geq$  35 kg/m2
- Scheduled for bariatric surgery
- Age  $\geq$  50 years
- Written informed consent.

### **Exclusion criteria**

Known cardiac disease.

# Study design

# Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	200
Туре:	Anticipated

### **IPD** sharing statement

Plan to share IPD: Yes

# **Ethics review**

Positive opinion	
Date:	
Application type:	

01-05-2020 First submission

# **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
NTR-new	NL8635
Other	MEC-U : R20.037

# **Study results**