# Atrial Fibrillation detection in OBESity using E-health

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To assess the prevalence of subclinical AF in obesity patients by using different contemporary AF-detection applications (primary objective). To investigate the potential role of GLS as a parameter to predict presence of AF in obesity patients (...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON56149

**Source**
ToetsingOnline

**Brief title**
AF OBESE

### Condition

- Other condition
- Cardiac arrhythmias

**Synonym**
Atrial fibrillation in obesity; heart rhythm disturbance in severe overweight patients

**Health condition**

obesitas

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Cardiologie
**Source(s) of monetary or material Support:** Stichting BOF (Bevordering Onderzoek Franciscus)

## Intervention

**Keyword:** Atrial fibrillation, Cardiac dysfunction, Obesity

## Outcome measures

### Primary outcome

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).

In 40 obesity patients with an increased CHA2DS2VASc-score who received both an AF-detection patch and an ILR, the proportions of patients with AF as detected by 1 week heart rhythm registration with the patch or 3 months with the ILR (before bariatric surgery) will also be explored. Results will be presented in a descriptive manner.

GLS (mean ± standard deviation) at baseline (before bariatric surgery) will be compared between obesity patients with versus without AF as identified by the AF-detection patch and/or ILR.

### Secondary outcome

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

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

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.

### Study objective

To assess the prevalence of subclinical AF in obesity patients by using different contemporary AF-detection applications (primary objective). To investigate the potential role of GLS as a parameter to predict presence of AF in obesity patients (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 burden and risks

For this study, patients will have to undergo some extra tests. However, the echocardiogram and AF-detection patch are considered harmless and the blood samples will be taken from a venapunction that will be performed anyway for clinical reasons. The amount of blood taken for the extra blood samples (total of 22 ml per visit) does not imply any risk for the patient. Only the subset of patients that will receive an ILR has to make an extra visit to the hospital. In a recent study it was shown that there were no major complications in patients undergoing ILR implantation. As obesity is one of the most important public health problems in the Western world and the prevalence of AF is increasing, the risk to and burden for the subjects will be in proportion to the potential value of the research.

## Contacts

**Public**
Selecteer

Kleiweg 500
Rotterdam 3045 PM
NL
**Scientific**
Selecteer

Kleiweg 500
Rotterdam 3045 PM
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

### Inclusion criteria

BMI of >= 35 kg/m2 and scheduled for bariatric surgery, age >= 50 years and written informed consent.

### Exclusion criteria

Known cardiac disease.

## Study design

### Design

**Study type:** Observational invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Basic science |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 23-09-2020 |
| Enrollment: | 200 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | Insertable loop recorder |
| Registration: | Yes - CE intended use |

## Ethics review

Approved WMO

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| Date: | 14-07-2020 |

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| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 17-11-2020 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 09-11-2023 |
| 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 | NL73987.100.20 |
| Other | NL8635 |