# Detection of Asymptomatic Atrial Fibrillation in persons of 65 year of age or older

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The smartphone connected MED as AAF is a valid screening instrument for application in transmural care in the Netherlands.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON25405

**Bron**
Nationaal Trial Register

**Verkorte titel**
DETECT AF

**Aandoening**

Asymptomatic Atrial Fibrillation
AAF
AF
Asymptomatisch atriumfibrilleren

### Ondersteuning

**Primaire sponsor:** Diagram B.V
Dokter Stolteweg 96
8025 AZ Zwolle
The Netherlands
**Overige ondersteuning:** Pfizer

Daiichi-Sankyo

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Primary objective:<br>
The aim of this study is to determine the accuracy, sensitivity and specificity of the AliveCor Kardia automated AF algorithm in a transmural care setting in the Netherlands. In patients ≥65 years without symptoms associated with (A)AF.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Rationale:

Atrial fibrillation (AF) is the most common cardiac arrhythmia. Although the condition itself is not life-threatening, the complications result in increased morbidity and mortality. AF is often asymptomatic and a considerable number of people suffering from AF are not aware of their condition. Unfortunately, a cerebral infarction is often the first clinical manifestation. The idea to screen persons opportunistically for Asymptomatic Atrial Fibrillation (AAF) was infeasible until recently. However, with a recently-developed smartphone connected Mobile ECG Device (MED), this seems to be feasible after all.

Study design:

A non WMO obligation, prospective study to examine the feasibility of screening persons of ≥ 65 year old for AAF.

Study population:

The study population will consist of a large group of people with not known AF until the screening.

Main study parameters/endpoints:

• To examine the feasibility of screening persons ≥65 years old for AAF

• To validate the smartphone connected MED as AAF screening instrument for application in transmural care in the Netherlands.

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Data collection:

The following data will be collected: age, gender, screening location, reason for screening, CHA2DS2-VASc score, sECG, sECG algorithm outcome, expert team sECG rhythm assessment , “sECG algorithm outcome vs observer assessment outcome” variability and “sECG inter-observer assessment” variability.

Nature and extent of the burden and risks due to participation:

The screening for this study will be combined with to determined visit of candidates to their family doctor or another event. The candidates have to give digital informed consent and will be asked to answer a minimum of questions (age, gender, screeninglocation, reason for screening, CHA2DS2-VASc score). Than an ECG will be made with the MED by holding a little stick with both hands.

If the automated MED automated AF algorithm gives “normal ECG” as result the study will end for the candidate.

If the MED gives “abnormal ECG” as result patient will be referred to medical healthcare for AF for further investigation and probable AF treatment.

For the study there will be no further investigation or follow-up.

All sECGs will be analysed by the sECG-expert team, if abnormalities are observed by this team the family doctor will be informed. The family doctor has the connection between the sECG code and the patient details and will contact the patient.

**Doel van het onderzoek**

The smartphone connected MED as AAF is a valid screening instrument for application in transmural care in the Netherlands.

**Onderzoeksopzet**

screening for AAF with mobile ECG device at T=0. After screening for AAF the study is ended for the patient

**Onderzoeksproduct en/of interventie**

screening persons ≥65 years old for AAF (Asymptomatic Atrial Fibrillation)

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

 -Age ≥65 years

 -Is giving informed consent

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-Known medical history with Atrial Fibrillation

 -Not mental competent

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 15-03-2018 |
| Aantal proefpersonen: | 4000 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 19-02-2018 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL6854 |
| NTR-old | NTR7032 |
| Ander register | METC Isala : 171010 |

# Resultaten