# Device-based rate versus rhythm control treatment in patients with symptomatic recent-onset atrial fibrillation in the emergency department (RACE 9)

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effectiveness (presence of sinus rhythm) of a watchful-waiting approach, i.e. symptom reduction through rate-control medication and monitoring until spontaneous conversion is achieved compared to routine care, consisting of either early or delayed…

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Cardiac arrhythmias |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON55214

**Source**
ToetsingOnline

**Brief title**
RACE 9 OBSERVE-AF

### Condition

- Cardiac arrhythmias

**Synonym**
atrial fibrillation, cardiac arrhythmia

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Medisch Universitair Ziekenhuis Maastricht

**Source(s) of monetary or material Support:** NWO;ZonMW,Hartstichting

## Intervention

**Keyword:** atrial fibrillation, rate control, rhythm control, telemonitoring

## Outcome measures

### Primary outcome

the primary endpoint is the presence of sinus rhythm on the electrocardiogram (ECG) at 4 weeks.

### Secondary outcome

Secondary endpoints are the number of transmissions from the telemonitoring infrastructure, accuracy of the automatic red-amber-green alert system, AF recurrences and progression, adverse events, costs, quality of life and predictive value of extended electrocardiography for AF progression and spontaneous conversion.

# Study description

### Background summary

until recently standard of care for patients with recent-onset atrial fibrillation (AF) was early cardioversion. This has just been expanded with a delayed cardioversion approach. However, considering the recurrent and transient nature of AF, cardioversion might not be needed at all and rate control medication might be sufficient to accomplish spontaneous conversion to sinus rhythm.

### Study objective

effectiveness (presence of sinus rhythm) of a watchful-waiting approach, i.e. symptom reduction through rate-control medication and monitoring until spontaneous conversion is achieved compared to routine care, consisting of either early or delayed cardioversion.

### Study design

a multicentre prospective, randomized, open label, non-inferiority trial comparing the interventional watchful-waiting approach to routine care (control).The primary endpoint (presence of sinus rhythm), will be assessed after 4 weeks. The total follow-up time is 1 year.

### Intervention

the watchful-waiting approach consists of administration of rate control medication to obtain relief of symptoms and a heart rate <110 beats per minute, followed by a telemetric rhythm monitoring period of four weeks to guide rate control therapy.

### Study burden and risks

the watchful-waiting approach may obviate the need for cardioversion, improve resource utilization in EDs, avoid overtreatment with cardioversion and therewith reduce disease burden. In addition to routine care, no additional visits are required for patients in the interventional group. All patients will be asked to use the telemetric monitoring device three times daily for four weeks to guide rate control. Patients will be asked to fill out questionnaires at baseline, and after 1, 6 and 12 months.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

• ECG with atrial fibrillation within 6 hours from presentation to the ED
• Duration of the AF episode <36 hours
• Symptoms due to atrial fibrillation
• Age > 18 years
• Able and willing to sign informed consent
• Able and willing to use telemetric rhythm recorder

### Exclusion criteria

• History of persistent AF (episode of AF lasting more than 48 hours and terminated by cardioversion)
• Deemed unsuitable for participation by attending physician
• Hemodynamic instability (heart rate >170 bpm, systolic blood pressure <100 mmHg)
• Acute heart failure
• Signs of myocardial infarction
• History of syncope of unexplained origin
• History of untreated Sick Sinus Syndrome
• History of untreated Wolff-Parkinson-White syndrome
• Currently enrolled in another clinical trial

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Parallel |

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| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 16-11-2020 |
| Enrollment: | 490 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 02-10-2020 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 23-04-2021 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 13-08-2021 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 18-02-2025 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

# 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 |
|---|---|
| ClinicalTrials.gov | NCT04612335 |
| CCMO | NL73104.068.20 |