

# Device-based Rate Versus Rhythm Control in Symptomatic Recent-onset Atrial Fibrillation (RACE 9 OBSERVE-AF)

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON22526

### Source

NTR

### Brief title

RACE 9 Observe-AF

### Health condition

Atrial fibrillation

## Sponsors and support

**Primary sponsor:** MUMC+

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

## Intervention

## Outcome measures

### Primary outcome

Presence of sinus rhythm on ECG after 4 weeks

### Secondary outcome

Implementation of the telemonitoring infrastructure, MACCE, AF recurrences/progression, cost-effectiveness, quality of life, patient reported outcome measures

## Study description

### Background summary

Continuous heart rhythm monitoring elucidated the recurrent and transient nature of recent-onset atrial fibrillation (AF). The RACE7 ACWAS showed that a wait-and-see approach (WAS) in patients with recent-onset AF (rate control for symptom relief followed by delayed cardioversion if needed <48h) allows spontaneous conversion to sinus rhythm in 69% of patients, obviating active cardioversion. Recurrences within one month were seen in 30% of patients in both groups, i.e. the initially chosen strategy did not affect the recurrence pattern. Considering the latter, it remains unclear whether cardioversion is needed at all, especially since cardioversion strategy does not seem to affect behaviour of the arrhythmia over time. Instead of cardioversion a watchful-waiting rate control strategy may be appropriate as initial strategy. This allows observing the electrical and clinical behavior of arrhythmia, providing a solid basis for comprehensive and effective early rhythm control. This study is a multi-center clinical randomized controlled trial to show non-inferiority of watchful-waiting with rate control versus routine care in terms of prevalence of sinus rhythm at 4 weeks follow-up, using a novel telemonitoring infrastructure to guide rate and rhythm control during follow-up.

### Study objective

The watchful waiting strategy is non-inferior compared to routine care in terms of effectiveness (presence of sinus rhythm on ECG after 4 weeks) in patients with recent-onset, symptomatic atrial fibrillation.

### Study design

Patients will have a follow-up visit after 4 weeks. Total follow-up duration will be one year.

### Intervention

watchful waiting

## Contacts

### Public

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**Scientific**

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## Eligibility criteria

### Inclusion criteria

Age > 18 years, ECG with atrial fibrillation, duration current episode <36 hours, symptoms due to AF, able and willing to sign informed consent, able and willing to use telemonitoring infrastructure

### Exclusion criteria

History of persistent AF, signs of myocardial infarction, signs of acute heart failure, hemodynamic instability, history of (untreated) sick sinus syndrome or Wolff-Parkinson-White syndrome, history of (unexplained) syncope, deemed unsuitable by attending physician, currently enrolled in another clinical trial

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	16-11-2020

Enrollment: 490  
Type: Anticipated

## IPD sharing statement

**Plan to share IPD:** Yes

### Plan description

All elements from the CRF matching a future project's CRF may be provided for an aggregated analysis

## Ethics review

Positive opinion  
Date: 16-04-2021  
Application type: 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	NL9416
Other	METC UM/aZM : METC 20-017

## Study results

### Summary results

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