Comparison between acute restoration of normal sinus rhythm and a wait-and-see-approach until spontaneous restoration of normal sinus rhythm in patients with acute symptomatic atrial fibrillation (ACWAS-trial).

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23118

Source
Nationaal Trial Register

Brief title
ACWAS

Health condition

Atrial fibrillation, irregular heartbeat, electrical cardioversion, pharmacological cardioversion. Boezemfibrilleren, atriumfibrilleren, onregelmatige hartslag, elektrische cardioversie, farmacologische cardioversie.

Sponsors and support

Primary sponsor: Maastricht University Medical Center (MUMC+)
Source(s) of monetary or material Support: ZonMw DoelmatigheidsOnderzoek

Intervention

Outcome measures

Primary outcome

Percentage of patients in sinus rhythm on 12-lead ECG at 4 weeks after index visit.

Secondary outcome

- Variance in outcome parameter associated with gender, time of presentation

- Time to recurrence of AF (MyDiagnostick 4 weeks, hospital records 1 year)

- AF-burden during 4 weeks following index visit (MyDiagnostick)

- Number of recurrent paroxysms during 1 year

- Total number of adverse events associated with primary visit

- Hospitalization for stroke/TIA, emboli, bleeding, myocardial infarction, PCI/CABG and other arrhythmias during follow up

- All-cause mortality

- Biomarkers, DNA-analysis and ECG parameters

- Safety assessment

- Prediction of spontaneous conversion

- Prediction of AF-recurrence

- Correlation AF progression

- Quality of Life

- Total health care consumption

- Total health care expenditure

- Total societal costs

Study description

Background summary

Rationale: Current guidelines recommend immediate cardioversion for patients with atrial fibrillation in the emergency department, while atrial fibrillation terminates spontaneously in 70% of the cases within 24 hours. A wait-and-see approach with rate-control medication only and when needed cardioversion within 48 hours of onset of symptoms could be effective, safe and more cost-effective than current standard of care.

Objective: Effectiveness (sinus rhythm), safety, and cost-effectiveness of a wait-and-see approach (WASA), consisting of symptom reduction through medication until spontaneous conversion is achieved, versus standard of care (acute cardioversion) for patients with symptomatic recent onset atrial fibrillation (AF) presenting at the emergency department (ED).

Study design: Randomized controlled non-inferiority trial in which a wait-and-see approach is compared directly to the standard of care. Total follow-up time is 1 year.

Study population: Patients with recent onset symptomatic AF at ED, age >18 years, suitable for both acute cardioversion and the wait-and-see approach.

Intervention: Wait-and-see approach (WASA), i.e. reduction of symptoms through adequate medication until spontaneous conversion to sinus rhythm, with delayed cardioversion if necessary.

Main study parameters/endpoints: Primary: presence of sinus rhythm on ECG at 4 weeks. Secondary: total costs, adverse events, and quality of life during 1 year.

Study objective

A Wait and See-approach is non-inferior on percentage of patients in sinus rhythm at 1 month as compared to acute cardioversion, but leads to a higher quality of life and less costs.

Study design

In intervention group only: Visit to outpatient clinic within 48 hours after index visit

All patients:

Visit at 1 month (questionnaires, ECG: primary outcome). Questionnaires at 6 and 12 months.

Intervention

A wait and see-approach, consisting of rate control drugs. Within 48 hours, patients will report to the outpatient clinic to check for spontaneous conversion to sinus rhythm.

Contacts

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Eligibility criteria

Inclusion criteria

- ECG with atrial fibrillation at the emergency department

- Heart rate > 70bpm

- Symptoms most probable due to atrial fibrillation

- Duration of symptoms < 24 hours

- > 18 years of age

- Able and willing to sign informed consent

- Able and willing to use MyDiagnostick

Exclusion criteria

- Signs of myocardial infarction on ECG

- Hemodynamic instability (systolic blood pressure < 100mmHg, heart rate > 170 bpm)

- Presence of pre-excitation syndrome

- History of Sick Sinus Syndrome

- History of unexplained syncope

- Acute heart failure

- Deemed unsuitable for participation by attending physician

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2014
Enrollment:	437
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-07-2014
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	NL4528
NTR-old	NTR4663
Other	: ABR: NL47065.068.13

Study results