Acute Cardioversion versus Wait And See-approach for symptomatic atrial fibrillation in the emergency department (ACWAS-trial)

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The objective of this study is to compare current standard of care for patients with symptomatic recent onset atrial fibrillation, which consists of pharmacological and/or electrical cardioversion, with a wait-and-see approach which consists of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON47614

Source
ToetsingOnline

Brief title
ACWAS-trial

Condition

- Cardiac arrhythmias

Synonym
Atrial fibrillation, irregular heartbeat

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW Doelmatigheidsonderzoek aangevraagd,Eigen middelen

Intervention

Keyword: Atrial fibrillation, Cardioversion, Emergency department

Outcome measures

Primary outcome

Sinus rhythm (SR) at 1 month after inclusion

Secondary outcome

-AF-burden (MyDiagnostick)

-Hospitalization for stroke/TIA, emboli, bleeding, myocardial infarction,

PCI/CABG, arrhythmia

-All cause mortality

-Biomarkers (safety and predictors of conversion/maintenance of SR)

-QoL

-Cost-effectiveness

Study description

Background summary

Atrial fibrillation (AF) is the most prevalent sustained cardiac arrhythmia and is responsible for substantial morbidity, mortality and (subsequent) economic costs. It is characterized by complety irregular heart rhythm, absent atrial contraction, and no distinct P-waves on the electrocardiogram. AF can cause heart failure and thrombus formation which explains the increased ischemic stroke risk. The emergency department (ED) is often where (symptomatic) AF is first detected and where patients present with recurrent attacks. Possible symptoms are palpitations, fatigue, weakness, dizziness, dyspnea, angina, and (pre)syncope. Current standard of care for patients with symptomatic AF in the ED is aimed at urgent restoration of sinus rhythm (i.e. cardioversion). This is usually achieved by pharmacological cardioversion, electrical cardioversion or

a combination of both. Electrical cardioversion is stressful for patients because of the requirement of general anesthesia and the after-effects hereof. It is furthermore costly as patients stay in the emergency department for a prolonged period of time and presence of both a cardiologist, for the conversion, and an anesthesiologist, for anesthesia, is required. Although immediate cardioversion of patients is proven to be safe and effective in acute restoration of sinus rhythm, one could question the need for immediate cardioversion as AF is a condition that resolves spontaneously within 24 hours in over 70% of the cases. In addition, its symptoms can succesfully be alleviated with medication that lowers the heart rate (rate control). In this age of rising health care costs, optimizing the use of available resources is important. Based on the beforementioned considerations, a newly proposed strategy would be to alleviate the symptoms of AF through adequate rate control medication, thereby bridging the time to spontaneous conversion to sinus rhythm. If sinus rhythm is not spontaneously achieved within 48 hours after onset of symptoms, electrical cardioversion can still safely be performed. This wait-and-see approach with delayed cardioversion as needed, would lower the need for cardioversions in the emergency department. Obviously, this may lower health care costs and decrease strain on the emergency department. Furthermore, patient disease burden could be lowered and patient disease perception improved. The latter relates to avoiding a burdensome intervention which is potentially unnecessary, leading to less time spent in the hospital, less adverse events and a lower psychosocial impact. This study aims to compare the wait-and-see approach (symptom alleviation and delayed cardioversion when necessary) to standard of care (immediate cardioversion). Outcome measures are chosen to prove efficacy, safety, cost-effectiveness and improved quality of life.

Study objective

The objective of this study is to compare current standard of care for patients with symptomatic recent onset atrial fibrillation, which consists of pharmacological and/or electrical cardioversion, with a wait-and-see approach which consists of symptom alleviation through rate control medication. All patients will receive appropriate anti-thrombotic management. Primary outcome measure is presence of sinus rhythm at 1 month after primary presentation. Secondary outcome measures are safety indicators including biomarkers, quality of life/patient perception and total cost of health care consumption during the following year. Main goal is to assess the potential for lowering health care costs, decreasing patient disease burden and stress on the emergency health care system while maintaining optimal patient care.

Study design

Patients at the emergency department (ED) with recent onset atrial fibrillation (AF) without signs of myocardial ischemia or hemodynamic instability are

eligible to participate. Patients will be informed about both treatment arms. Upon signing of informed consent, patients will be randomized into two groups. The control group will receive standard care. Pharmacological cardioversion (PCV) will be performed. In case of contra-indications, history of failing PCV or failure of PCV, electrical cardioversion (ECV) will be performed. The intervention group will receive symptomatic treatment. All patients will receive anti-thrombotic therapy as needed. Patients in the intervention group will visit the clinic within 48 hours after onset of AF. Patients who still have AF on ECG will undergo cardioversion (CV). In the following month, all patients will use a MyDiagnostick device 3 times daily to check for recurrence of AF. Patients will visit the outpatient clinic at 1 month to determine heart rhythm on ECG. Quality of Life (QoL), costs and medical events will be assessed at baseline, 1, 6, and 12 months.

Intervention

The intervention consists of a wait-and-see approach (WASA) with symptom reduction. A visit within 48 hours after onset of symptoms will be planned to check for conversion to SR. If AF is still present, active cardioversion will be performed.

Study burden and risks

The additional burden of the intervention arm of this trial versus standard of care consists of:
- At presentation at the ED, additional blood will be collected during the standard venapunction to determine biomarkers (in case the biomarkers are not necessary for clinical care at that point in time). Risks are negligeble.
- An extra visit to the hospital at 48 hours with an extra ECG-recording. This visit will take approximately 20 minutes if there has been spontenaous conversion, and 240 minutes if there is still atrial fibrillation. It should be kept in mind that the index visit was approximately 180 minutes shorter.

In both the intervention and control group, the additional burden consists of:
- During one month, three times daily, the use of a MyDiagnostick. This device can be used discreetly and does not interfere with daily activity. Each measurement takes 1 minute.
- At 1, 6 and 12 months after inclusion, patients will be asked to fill out Quality-of-life questionnaires. This will take 30 minutes. Questions will focus on quality of life, use of medical care and societal costs. The psychological burden of these questionnaires is expected to be low.

Patients included at the MUMC are asked for an additional blood sample, drawn during the visit at 1 month after index visit. For patients included in Diakonessenhuis, in case of consent on the full informed consent form, additional blood will be drawn by an additional venous puncture only for

DNA-analysis. For patients included in the other participated centers, in case of consent on the additional informed consent form, additional blood will be drawn by an additional venous puncture only for DNA-analysis.

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 at the emergency department, recorded by General Practicioner or recorded in Ambulance
• Heart rate > 70bpm
• Symptoms most probable due to atrial fibrillation
• Duration of symptoms < 36 hours
• > 18 years of age
• Able and willing to sign informed consent

• Able and willing to use MyDianostick

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
History of persistent AF (episode of AF lasting more than 48 hours)
Acute heart failure
Currently enrolled in another clinical trial
Deemed unsuitable for paticipation by attending physician

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-10-2014
Enrollment:	437
Type:	Actual

Ethics review

Approved WMO

Date:	04-08-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-06-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-04-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-06-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-08-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-10-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-06-2017
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
CCMO	NL47065.068.13

Study results

Date completed:	23-12-2019
Actual enrolment:	437