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).

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23118

Bron
Nationaal Trial Register

Verkorte titel
ACWAS

Aandoening

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

Ondersteuning

Primaire sponsor: Maastricht University Medical Center (MUMC+)
Overige ondersteuning: ZonMw DoelmatigheidsOnderzoek

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	437
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-07-2014
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	NL4528

Register	ID
NTR-old	NTR4663
Ander register	: ABR: NL47065.068.13

Resultaten