Home based cardioversion, feasible and safe?

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Home DC-ECV in general population patients with an episode of symptomatic recurrent persistent AF, carried out by ECPs, is feasible, safe and is associated with reduced costs.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26484

Bron
Nationaal Trial Register

Verkorte titel
RACE-6

Aandoening

Symptomatic recurrent persistent Atrial fibrillation
Electro cardiversion
Home based cardiac intervention
Emergency Care Practitioners
In Dutch:
Recidief symptomatisch persisterend atriumfibrilleren
Electrische cardioversie
Cardiale thuisinterventie
Verpleegkundig specialist acute zorg

Ondersteuning

Primaire sponsor: Academisch ziekenhuis Maastricht (azM)
Overige ondersteuning: Fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

In this observational feasibility and safety study in 30 patients the
(a) feasibility endpoint is completion of cardioversion (% of study patients with a recurrence of AF in whom a home cardioversion is performed, i.e. to whom at least one DC countershock was administered while the patient was under deep sedation;
(b) safety endpoint: a composite of major adverse cardiovascular and cerebrovascular events (MACCE) occurring within 24 hours (subdivided in early MACCE, i.e. during the first hour observation period and late MACCE, i.e. thereafter up till 24 hours).

completion of cardioversion (% of study patients with a recurrence of AF in whom a home cardioversion is performed, i.e. to whom at least one DC countershock was administered while the patient was under deep sedation);

Toelichting onderzoek

Achtergrond van het onderzoek

Atrial fibrillation (AF) is common daily practice in hospitals and is associated with significant morbidity and mortality. Its economic burden is high in the affluent countries. Direct-current electrical cardioversion (DC-ECV) is one of the methods to restore sinus rhythm in patients which usually takes place in a Cardiology Department. Nowadays prompt service is hard to provide in many institutions due to logistic difficulties around DC-ECV (shortage of beds, limited number of personnel, problematic control of the INR and workload of the staff).

The Dutch government tries to realize a shift in treatment of patients from the clinical setting to the primary setting. The focus lies on treatments that not necessarily have to take place in the hospital. A shift to the primary setting (i.e. primary care physicians, emergency care practitioners) is thought to reduce costs while maintaining high quality of care. In addition, (medical) care becomes more and more focused on the needs and wishes of the patient. Since January 2012 Emergency Care Practitioners (ECPs) are qualified (under certain conditions) to perform elective cardio versions.

The present pilot study is designed in order to assess both feasibility and safety of home DC-ECV in the management of recurrent symptomatic persistent AF performed by emergency care practitioners (ECPs). Cost-efficacy will also be analysed.

Doel van het onderzoek

Home DC-ECV in general population patients with an episode of symptomatic recurrent persistent AF, carried out by ECPs, is feasible, safe and is associated with reduced costs.

Onderzoeksopzet

The primary endpoint will be recorded on day 1 of the study, i.e. the day of the DC electrical cardioversion.

The secondary endpoints will be recorded as follows:

- MACCE at 24 hours and at the end of follow-up after 6 weeks.

- percentage of patients in sinus rhythm at 1 hour after DC electrical cardioversion and at the end of 6 weeks follow-up

- the inventory of all interventions as well as study related to costs-of-care will be collected at the end of 6 weeks follow-up

Onderzoeksproduct en/of interventie

Race-6 is an observational pilot study during 6 weeks, without a control group. The intervention deployed is a standard electrical cardioversion performed in the home environment of the patients.

In detail: we will investigate the feasibility of home direct current electrical cardioversion (DC-ECV) in adult stable patients (n = 30) with recurrent persistent atrial fibrillation (AF). This is a prospective study of home-based DC-ECV using Corpuls3® equipment conducted by specialized emergency care practitioners (ECPs) after application of intravenous propofol for sedation. ECG before and after home DC-ECV procedure will be performed. Synchronized shocks of biphasic energy is applied by deployment of a maximum of four shocks of 200 Joules each with the electrode position placed at the anterolateral (AL) (= anterior-apex (AA)) site. Follow-up will be done at 6 weeks, comprising of telephone contact and, when needed, personal contact at 4 and 24 hours is conducted to monitor the recurrence of AF, complications and adverse events. In addition, the cost-effectiveness relationship of home (n = 30) versus a matched control group of hospital DC-ECV (n = 30) will be calculated. The total study is estimated to last 6 months.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria:

1.Signed informed consent;

2.Age 20-75 year subjects, able to understand the provided information and sign an informed consent;

3.Need for direct current electrical cardioversion (DC-ECV) for correction of recurrent symptomatic persistent AF (according to the guidelines of the American College of Cardiology/American Heart Association/European Society of Cardiology (ACC/AHA/ESC));

4.Weight more than 50 kilograms;

5.Successful hospital DC-ECV for a previous episode of persistent AF performed under propofol sedation;

6.Target range of international normalized ratio (INR) above 2.0, when on vitamin K antagonists, or use of novel oral anticoagulant, stable for 3 weeks;

7.ASA 1 and 2;

8.BMI < 35 kg/m2;

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

Exclusion criteria:

1.Patients over 75 years old and younger than 20;

2.Patients wearing pacemaker or implantable cardioverter-defibrillator;

3.Patients with (cardiovascular):

„Xsick sinus syndrome, ventricular pre-excitation, Brugada syndrome or bundle branch block

„Xsevere ischemic or valvular heart disease

„Xdilated or hypertrophic cardiomyopathy

„Xsecond or third degree atrioventricular block

„Xheart failure NYHA III or IV, known LVEF < 35%, or cor pulmonale

„Xtransient and reversible cause of AF, e.g. in setting of fever and hyperthyroidism

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2013
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39850
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3908
NTR-old	NTR4078
CCMO	NL42344.068.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39850

Resultaten

Samenvatting resultaten
The findings will be described in several articles and offered for publication in peer-reviewed scientific journals. A thesis will be prepared.