RegionAl Home CardiovErsion study of atrial fibrillation.
Pilot study on feasibility.

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The aim of this pilotstudy is to obtain data regarding feasibility, safety and costs of home-based electrical cardioversion

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

Summary

ID

NL-OMON50670

Source
ToetsingOnline

Brief title
RACE-6 study

Condition

- Cardiac arrhythmias

Synonym
Atrial Fibrillation, Supraventricular arrhythmia

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ambulance Oost

Intervention

Keyword: Atrial Fibrillation, Home based cardioversion, Rhythm control

Outcome measures

Primary outcome

There is one co-primary endpoint: 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 (propofol) sedation

Secondary outcome

Secondary endpoints: - safety endpoint: a composite of MACCE occurring within 24 hours - major adverse cardiovascular and cerebrovascular events (MACCE) occurring during 6 weeks follow-up - any hospitalisation and all-cause mortality during 6 weeks follow-up - number (%) of patients in sinus rhythm at 1 hour in the post-shock observation period - number (%) of patients in sinus rhythm at the end of 6 weeks follow-up - inventory of all interventions in the study related to cost-of-care.

Study description

Background summary

Atrial fibrillation (AF) is associated with significant cardiovascular morbidity and mortality, especially with ageing of the population. The economic impact of AF on health care resources is increasing significantly. Nowadays prompt service is hard to provide in many institutions due to logistic difficulties around cardioversion (shortage of beds, limited number of personnel, problematic control of the INR and workload of the staff). Based on previous international studies of outpatient management - successfully and safely conducted through either a nurse-led or a physician-led strategy - we

designed the present pilotstudy 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) on site supported by well trained and certified sedation practitioners from the Ziekenhuis Groep Twente. We postulate that this home policy is feasible and safe and associated with low costs compared to hospital-based cardioversion. This model will release the pressure on the limited number of acute hospital beds and unload the pressure of the heavily loaded junior staff members.

Study objective

The aim of this pilotstudy is to obtain data regarding feasibility, safety and costs of home-based electrical cardioversion

Study design

The study is designed as a pilot, open-label, non-controlled, non-randomised, multicentre study. Eligible patients who attended the Coronary Care Unit (CCU) of the participating hospitals in the Netherlands for elective day-case DC-ECV of symptomatic persistent atrial fibrillation are asked to participate in this pilot study, for a potential future home DC-ECV in case a recurrent episode occurs, after a previous successful in-hospital DC-ECV. Patients are included after giving written informed consent. The study is designed as a pilot, open-label, non-controlled, non-randomised, multicentre study. The RACE-6 pilot study is a prospective observational study (nurse-led home-based DC-ECV) which will be carried out in the Netherlands by well-trained and Sedation-certified emergency care practitioners (ECP's) of the ambulance service Ambulance Oost on site supported by well trained and certified Sedation Practitioners. The study is initiated and coordinated by Ambulance Oost, Hengelo, the Netherlands. Patients will be followed for 6 weeks for MACCE, costs and rhythm outcome.

Intervention

Compared to standard treatment for AF which consists of electrical cardioversion in the hospital, RACE-6 will study cardioversion performed at home. In fact this is an observational study applying a well known intervention (standard electrical cardioversion) in a new (non-standard) environment, i.e. at home.

Study burden and risks

The burden and risks are taken care of adequately and are well balanced by the benefits and future treatment possibilities for atrial fibrillation. Home cardioversion is a novel procedure. On one hand a reduction of the burden for the patient from management is foreseen since the new treatment is performed at the patient's home where all precautions are taken which are also active in the

hospital. Only stable patients who previously underwent the same procedure uneventfully in the hospital will be selected. All precautions and selections will prevent any complication but if such event happens, all measures can and will be taken which would also have been taken in the hospital. If needed the treatment can be taken over swiftly and adequately by the hospital.

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

In order to be included in the study, the patients need to have had a previous successful hospital DC-ECV under propofol sedation. Patients aged (20-75 years) with a recurrence of symptomatic persistent AF without hemodynamic instability or other severe co-morbidities requiring DC-ECV (according to ESC guidelines) are enrolled in the study, after prior uncomplicated hospital DC-ECV. A written

informed consent will be obtained.

Exclusion criteria

The exclusion criteria are as follows: Patients over 75 years old (and younger than 20 years), patients wearing pacemaker or implantable cardioverter-defibrillator and patients with severe co-morbidities (liver disease, kidney impairment, pulmonary dysfunction, malignancies, connective tissue disease, inflammatory disease such as peri-myocarditis) are excluded from participating in the study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-01-2019
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Defibrillator
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	20-12-2017

Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-05-2020
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	NL63041.068.17
Other	NTR TC=4078