Elective cardioversion of atrial fibrillation at home by advanced practice providers; A feasibility study in Dutch emergency medical service.

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In this prospective interventional feasibility study, we would like to assess the feasibility of a home DC-ECV in the treatment of recurrent symptomatic AF performed by APP in 25 patients.

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

Summary

ID

NL-OMON56551

Source
ToetsingOnline

Brief title
ELECTRA-1

Condition

- Cardiac arrhythmias

Synonym
atrial fibrilation

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch ziekenhuis
Source(s) of monetary or material Support: RAV Brabant MWN

Intervention

Keyword: Advanced Practice Provider, Emergency medical service, Home-Cardioversion

Outcome measures

Primary outcome

The main objectives of this feasibility study focuses on; (a) can a home DC-ECV be done, (b) evaluation of enrollment of participants, (c) evaluation and refinement of data and outcome collection procedures, (d) evaluation of logistics, (d) evaluation of the appropriateness of the intervention and research procedures to manage and implement the intervention, and (e) preliminary evaluation of participant responses to the intervention.

Secondary outcome

Secondary objectives:

Safety endpoint:

Complications immediately during and one hour after cardioversion (e.g. arrhythmias, changes in the electrocardiogram, hypotension related to sedation and/or vasodilation or skin irritation).

A composite of major adverse cardiovascular and cerebrovascular events (MACCE) occurring within 24 hours

MACCE occurring during 6 weeks follow-up; any hospitalisation and all-cause mortality during 6 weeks follow-up; ; idem 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 common daily practice in hospitals and when not treated it is associated with significant morbidity and mortality. Its economic burden is high in affluent countries. Direct current electrical cardioversion (DC-ECV) is one of the methods to restore patients' sinus rhythm, which is usually done in an emergency (cardiac) room or Coronary care unit. Nowadays, rapid service is difficult to achieve in many institutions due to logistical problems surrounding DC-ECV (shortage of beds, limited number of staff, problematic INR monitoring and staff workload).
The Dutch government is trying to achieve a shift in the treatment of patients from the inpatient services to outpatient services. The emphasis is on treatments that do not necessarily have to take place in the hospital. This shift, to the primary setting (i.e., general practitioners of medical emergency care practitioners) is supposed to reduce costs while maintaining a high quality of care. Moreover, (medical) care is increasingly focused on the needs and wishes of the patient with diagnostics, triage and possibly treatment close to the patient's home environment.
Since January 2019, advanced practice providers (APP), working at Emergency medical service (EMS) RAV Brabant MWN perform "procedural sedation and analgesia"(PSA), the sedation is applied to enable short, very painful procedures or to reduce agitation. This offers an opportunity to organize a DC-ECV outside the hospital.

Study objective

In this prospective interventional feasibility study, we would like to assess the feasibility of a home DC-ECV in the treatment of recurrent symptomatic AF performed by APP in 25 patients.

Study design

This study is designed as a pilot, non-controlled, non-randomised, single centre study. The Electra-1 pilot study is a prospective intervention feasibility study.

Intervention

Instead of the regular clinical treatment, in this study direct-current electrical cardioversion (DC-ECV) will be performed at the patient's home and will be carried out by well-trained and certified advanced practice providers (APP) on site, i.e. nurse practitioner or physician assistant, supported by an EMS ambulance team containing an ambulance nurse and ambulance driver, both trained advanced life-support (ALS) professionals.

Study burden and risks

The study is designed to reduce the burden of DC-ECV by treating patients in their own environment.
Home DC-ECV is an intervention that is performed in exactly the same way as in the clinical setting; the performers are, however, not a medical specialist, but well trained and qualified APP*s and ambulance professionals.
By various precautions, such as targeted education/training of the APP*s, telephonic back-up from medical specialists and presence of ambulance professionals, the risk of home DC-ECV is minimized.

Contacts

Public
Jeroen Bosch ziekenhuis

Henri Dunantstraat 1
's-Hertogenbosch 5223GZ
NL
Scientific
Jeroen Bosch ziekenhuis

Henri Dunantstraat 1
's-Hertogenbosch 5223GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. 1. Signed informed consent 2. Age 18 -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 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 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 2 8. BMI < 35 kg/m2

Exclusion criteria

1. Patients over 75 years old and younger than 18 years 2. Patients wearing pacemaker or implantable cardioverter-defibrillator. 3. Patients with (cardiovascular): * sick sinus syndrome, ventricular pre-excitation, Brugada syndrome or bundle branch block * severe ischemic or valvular heart disease * known second or third degree atrioventricular block normal sinus rhythm * heart failure NYHA III or IV, known LVEF < 35%, or cor pulmonale * transient and reversible cause of AF, e.g. in setting of fever and hyperthyroidism 4. Patients with severe co-morbidities: a. liver disease b. kidney impairment (eGFR <= 30 according to formula MDRD) c. pulmonary dysfunction (FEV1 /VC <75% gold classification) d. active malignancy e. connective tissue disease f. inflammatory disease such as peri-myocarditis/endocarditis 5. Life expectancy less than 1 year 6. Patients with ventricular tachycardia or supraventricular arrhythmias 7. Patients with slow ventricular rate (< 55/min), bifascicular block 8. Contraindications to a sedation 9. Patients lacking family care at home 10. Pregnancy 11. ASA 3 & 4 12. BMI > 35 kg/m2

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	04-03-2024

Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	05-01-2024
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	16-09-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL83536.028.23