The ECV day-1 outcome for Atrial Fibrillation data collection: a retrospective analysis of outcomes on day-1 after electrical cardioversion

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27758

Source
NTR

Brief title
TED-AF

Health condition

Atrium fibrillation

Sponsors and support

Primary sponsor: Departments of Cardiology and Anesthesia, Amsterdam UMC, location AMC
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The number of patients with complications related to the anaesthesia or the ECV procedure between 0-2 and 2-24 hours after the procedure.

Secondary outcome

The occurrence of stroke/ complications up to 30 days after the ECV procedure.
The type, severity, treatment, and outcomes of the reported complications.

Study description

Background summary

Electrical cardioversion (ECV) is an effective treatment for patients with AF, restoring sinus rhythm in approximately 90% of cases.The Amsterdam University Medical Center (Amsterdam UMC), location AMC, treats more than 500 patients with an elective ECV, per year. If the patients feel well enough, they are discharged to their home environment, under supervision for the first evening and night.

Research question
Is it safe for patients who have undergone an elective ECV in the AMC, to spend the first evening and night alone at home, without additional supervision?

For this retrospective outcome analysis, “safe” is defined as the absence of complications related to the anaesthesia or the cardioversion, in the first 24 hours after the ECV procedure.

Study objective

Is it safe for patients who have undergone an elective ECV in the AMC, to spend the first evening and night alone at home, without additional supervision?

Study design

Timepoint 1: Baseline measurements: cardiac rate, rhythm, and other cardiac variables, before ECV.
Timepoint 2: 0-2 hours after ECV: cardiac rate and rhythm, adverse events or complications, their type, severity, treatment, and outcome, measured until discharge from hospital.
Timepoint 3: 2-24 hours: any adverse events or complications as a result of the anesthesia or ECV, their type, severity, treatment, and outcome, measured from discharge until 24 hours after ECV.
Timepoint 4: 30 days: Any adverse events or complications as a result of the anesthesia or ECV, their type, severity, treatment, and outcome, measured between 24 hours and one month after the procedure.

Intervention

None, observational

Contacts

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Eligibility criteria

Inclusion criteria

- Patients who underwent ECV in Amsterdam UMC, location AMC in 2019 and 2020
- Patients > 18 years

Exclusion criteria

- Patients who completed an objection to the re-use of care data.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-04-2021
Enrollment:	500
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	15-04-2021
Application type:	First submission

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
NTR-new	NL9433
Other	METC Amsterdam UMC, location AMC : W21_151#21.166, confirmed as non-WMO study

Study results