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

Gepubliceerd: 15-04-2021 Laatst bijgewerkt: 18-08-2022

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?

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27758

Bron
NTR

Verkorte titel
TED-AF

Aandoening

Atrium fibrillation

Ondersteuning

Primaire sponsor: Departments of Cardiology and Anesthesia, Amsterdam UMC, location AMC
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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?

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

None, observational

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-04-2021
Aantal proefpersonen:	500
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	15-04-2021
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	NL9433

Register	ID
Ander register	METC Amsterdam UMC, location AMC : W21_151#21.166, confirmed as non-WMO study

Resultaten