POMPAE trial. Peri-Operative Magnesium infusion to Prevent Atrial fibrillation Evaluated.

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Perioperative magnesium infusion (maintaining a serum concentration between 1.5-2.0 mmol/L) is able to clinically significantly reduce the incidence of perioperative atrial fibrillation (POAF).

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

Samenvatting

ID

NL-OMON24637

Bron
Nationaal Trial Register

Verkorte titel
POMPAE

Aandoening

Atrial fibrillation

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: Internal hospital resources, no outside sponsoring

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Newly diagnosed AF over a period of 5 minutes or longer

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Post-operative atrial fibrillation (POAF) is commonly observed in patients post cardiac surgery without a previous history of atrial fibrillation (AF) or other arrythmias. It’s associated with significant postoperative complications including infection, bleeding reoperation, increased hospital length of stay (LOHS) and mortality. Magnesium has been identified as a potentially interesting compound with easy access and low toxicity. Hypomagnesemia has been observed frequently immediately after cardiac surgery. Both reduction of abnormal atomicity of atrial myocardium and prolongation of the atrial refractory period caused by administration of magnesium may prevent AF.
Objective: To investigate the effect of continuous (preceded by a bolus) administration of magnesium sulphate (Mg2SO4) in the perioperative phase on the incidence of POAF in patients undergoing cardiothoracic surgery.
Study design: Single-center, randomized placebo-controlled trial
Study population: Patient (18 years and older) undergoing elective cardiac surgery (Coronary Artery Bypass Surgery, CABG) and/or valve (any position(s)) surgery.
Intervention: Patients will be randomized to receive Mg2SO4 directly post induction of anesthesia until discharge from the Intensive Care Unit (ICU).
Main study parameters/endpoints: Measurement of the incidence of POAF in the first 7 days post-surgery has been defined as primary endpoints. Secondary endpoints include Length of Hospital stay (LOHS) and ICU Length Of Stay (LOS), duration of mechanical ventilation, inotropic and/or vasopressor support, combined outcome of 28-day mortality, stroke, pulmonary embolism, delirium (requiring anti-psychotic medication), infection requiring antibiotics and POAF.

Doel van het onderzoek

Perioperative magnesium infusion (maintaining a serum concentration between 1.5-2.0 mmol/L) is able to clinically significantly reduce the incidence of perioperative atrial fibrillation (POAF).

Onderzoeksopzet

First 28 days post-surgery

Onderzoeksproduct en/of interventie

Magnesium sulfate administration (preceded by a bolus based on serum measurement) initiated directly post induction of anesthesia until ICU discharge.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Elective cardiac surgery (valve surgery and/or CABG)
- 18 years and above

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- History of atrial fibrillation (AF) and atrial flutter
- Concomitant procedures (MAZE (surgical ablation)/PVI (pulmonary vein isolation))
- Pre-existing severe renal impairment (eGFR<30 ml/min) or development of oliguria post-surgery (<200 ml in previous 6 hours) and/or rise in creatinine with eGFR <30 ml/min)
- Significant hypotension persisting for 1 hour or longer (Noradrenaline >0.1 mcg/kg/min)
- Third-degree heart block without pacemaker in situ

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2022
Aantal proefpersonen:	812
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL9810
Ander register	METC Leiden-Den Haag-Delft. (METC LDD) : Following

Resultaten