Peri-operative Magnesium infusion to Prevent Atrial fibrillation Evaluated.

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In patients undergoing cardiothoracic surgery, to investigate the effect of continuous (preceded by a bolus) administration of perioperative magnesium sulphate (MgSO4) on the incidence patients with POAF.

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

Summary

ID

NL-OMON54180

Source
ToetsingOnline

Brief title
POMPAE trial

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation, cardiac arrhythmia

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: subsidie vanuit het HagaZiekenhuis

Intervention

Keyword: Atrial fibrillation, Magnesium infusion, Placebo, Prevention

Outcome measures

Primary outcome

Measurement of the incidence patients with POAF in the first 7 days

post-surgery has been defined as primary endpoint.

Secondary outcome

Secondary endpoints include duration of POAF, peak heart rate during POAF,

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.

Study description

Background summary

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.

Study objective

In patients undergoing cardiothoracic surgery, to investigate the effect of continuous (preceded by a bolus) administration of perioperative magnesium

sulphate (MgSO4) on the incidence patients with POAF.

Study design

Single-center, randomized placebo-controlled trial.

Intervention

Patients will be randomized to receive MgSO4 (bolus of 10 mmol and continuous infusion of 3 mmol/hour MgSO4 depending on serum Mg2+ level or Ringer*s lactate initiated directly post induction of anesthesia until discharge from the Intensive Care Unit (ICU). Magnesium levels in the OR and ICU are maintained above 1 mmol/L as part of general care. Magnesium levels thresholds for the POMPAE study are maintained between 1.5 and 2.0 mmol/L.

Study burden and risks

Magnesium is regularly administrated post-cardiac surgery to maintain a serum level above 1 mmol/L. Adverse events regarding magnesium administrations are rare and toxicity occurs at levels above 2.0-2.5 mmol/L. From treatment regimens for preeclampsia, plasma levels of 2.5-3.5 mmol/L or higher are achieved regularly. Therefore, signs of hypermagnesemia (lethargy, somnolence, absent tendon reflexes, bradycardia, and ECG changes) will be monitored. As the study is performed in both the operating theater and ICU and magnesium levels are monitored regularly with toxicity generally occurring with significantly higher than desired serum levels, the risk for participating patients is deemed low.

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

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

Exclusion criteria

- History of atrial fibrillation (AF) or atrial flutter
- Concomitant rhythm associated 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)
- Development of third-degree heart block during index admission or pre-existing 3rd degree heart block without pacemaker presence.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-08-2022
Enrollment:	530
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	MgSO4
Generic name:	magnesium sulphate
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	08-04-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	09-11-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	09-03-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	13-04-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	15-04-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
EudraCT	EUCTR2022-001393-58-NL
ClinicalTrials.gov	NCT05669417
CCMO	NL77956.058.21