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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24637

Source
Nationaal Trial Register

Brief title
POMPAE

Health condition

Atrial fibrillation

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: Internal hospital resources, no outside sponsoring

Intervention

Outcome measures

Primary outcome

Newly diagnosed AF over a period of 5 minutes or longer

Secondary outcome

1. 28-day AF post-surgery.
2. Length of Hospital Stay (LOHS) and ICU LOS
3. Duration of mechanical ventilation
4. Duration of inotropic or vasopressor support
5. Combined outcome including 28-day post-surgery mortality, stroke, pulmonary embolism, delirium (requiring any form and/or duration of anti-psychotic medication) and infection requiring antibiotics.

Study description

Background summary

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.

Study objective

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).

Study design

First 28 days post-surgery

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2022
Enrollment:	812
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

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

Study results