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Comparison of intravenous magnesium sulphate and intravenous esmolol in attenuating hemodynamic stress response during tracheal extubation

Submission date
26/09/2025

Recruitment status
No longer recruiting

Registration date
07/10/2025

Overall study status
Completed

Last Edited
07/10/2025

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Tracheal extubation is an important and integral procedure of general anesthesia. Tracheal extubation can lead to irritation of the airways, which may cause coughing, resulting in increased systolic and diastolic blood pressures (SBP and DBP) and an increase in intrathoracic pressure, potentially interfering with cardiac preload. Hypertensive subjects may exhibit an exaggerated response to tracheal extubation compared to normotensives. In patients with coronary artery disease, these changes can lead to myocardial ischaemia, left ventricular dysfunction, cardiac dysrhythmias, cerebral haemorrhage and reduction in ejection fraction. Esmolol is a short-acting, highly cardioselective beta-adrenergic receptor antagonist rapidly metabolized by plasma esterase. The rapid onset of action of esmolol prevents an acute increase in heart rate and arterial pressure, which occur at extubation. Magnesium is a naturally occurring calcium channel antagonist and a non-competitive antagonist of N-methyl D-aspartate (NMDA) receptor. The role of magnesium in blunting the hemodynamic response to endotracheal intubation and extubation is evolving. It has been shown that magnesium inhibits catecholamine release from adrenal medulla and adrenergic nerve endings. This study aims to compare esmolol and magnesium sulphate in attenuating hemodynamic response to extubation.

Who can participate?
Adult patients with no to mild systemic disease, aged 20-55 years

What does the study involve?
This study will involve patients undergoing surgery under general anaesthesia and who have been extubated at the end of the procedure. Participants will be randomly assigned to Group A to receive IV esmolol infusion 0.5 mg/kg diluted in 100 ml of normal saline over 10 minutes beginning 5 minutes pre-extubation, and Group B, who receive IV MgSO4 – 40 mg/kg diluted in 100 ml of normal saline over 10 minutes starting 5 minutes pre-extubation. It is a prospective

comparative study, meaning it will follow patients forward in time and compare outcomes between groups. The research will take place over two years, with full ethical approval and informed consent obtained from all participants.

What are the possible benefits and risks of participating?
Benefits and risks not provided at registration

Where is the study run from?
Department of Anaesthesiology and Critical Care, Era's Lucknow Medical College and Hospital, Lucknow, India.

When is the study starting and how long is it expected to run for?
February 2021 to July 2022

Who is funding the study?
Era's Lucknow Medical College and Hospital, Lucknow, India.

Who is the main contact?
Dr Asad Khalid, asadkhalid30@gmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Asad Khalid

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Comparison of intravenous magnesium sulphate and intravenous esmolol in attenuating hemodynamic stress response during tracheal extubation in patients undergoing surgery

Acronym
CMET

Study objectives
Which drug, between intravenous esmolol and intravenous magnesium sulphate, is better for attenuating hemodynamic response to tracheal extubation?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/02/2021, Era's Lucknow Medical College and Hospital Institutional Ethics Committee (Sarfarazganj, Hardoi Road, Lucknow, 226003, India; +919452810007; info@erauniversity.in), ref: ELMC&H/Rcell/EC/2021/101

Study design
Interventional double-blinded randomized parallel group

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Efficacy

Participant information sheet
Not available in web format, please use contact details to request participant information sheet

Health condition(s) or problem(s) studied
Haemodynamic stress response during tracheal extubation

Interventions
After surgery, operated patients were randomly assigned to groups A and B, with 40 individuals in each group using a computer-generated randomized table. After randomisation, Group A received IV esmolol infusion 0.5 mg/kg diluted in 100 ml of normal saline over 10 minutes beginning 5 minutes pre-extubation, whereas Group B received IV $MgSO_4$ – 40 mg/kg diluted in 100 ml of normal saline over 10 minutes starting 5 minutes pre-extubation. If the patient experienced an adverse effect, the infusion was halted, and the patient was treated accordingly. After restoring neuromuscular inhibition and suctioning, subjects were extubated. Study vitals (SBP, DBP, MAP, and HR) were recorded before extubation, at the time of extubation, 5 mins, 10 mins and 15 mins post extubation

Intervention Type
Drug

Pharmaceutical study type(s)
Fixed dose response in 2 different drug groups at different points of time in multiple parameters

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Esmolol, magnesium sulphate

Primary outcome measure
SBP, DBP, MAP and HR measured using a blood pressure cuff at baseline, at the time of intervention, 5, 10, and 15 minutes post-intervention

Secondary outcome measures
SBP, DBP, MAP and HR measured before giving the drug using a blood pressure cuff, at the time of intervention, 5, 10 and 15 minutes post-intervention in both parallel study groups

Overall study start date
17/02/2021

Completion date
31/07/2022

Eligibility

Key inclusion criteria
1. ASA Grade-I and Grade-II patients, age 20-55 years, weight 40-75 kg
2. Patients undergoing surgery under General Anaesthesia, who will be extubated at the end of surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
20 Years

Upper age limit
55 Years

Sex
Both

Target number of participants

80

Total final enrolment
80

Key exclusion criteria
1. Patients with an allergy to study drugs
2. Patients with ASA grade 3 or more
3. Patients taking any adrenergic or psychotropic drugs
4. Patients with hepatic or renal disease
5. Patients with lung disease such as COPD

Date of first enrolment
23/02/2021

Date of final enrolment
23/02/2021

Locations

Countries of recruitment
India

Study participating centre
Era's Lucknow Medical College and Hospital
Sarfarazganj
Lucknow
India
226003

Sponsor information

Organisation
Era's Lucknow Medical College and Hospital

Sponsor details
Sarfarazganj, Hardoi Road
Lucknow
India
226003
+91 0522-6600777
info@elmcindia.org

Sponsor type
Hospital/treatment centre

Website
https://elmcindia.org/

ROR
https://ror.org/01df9ep43

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Era's Lucknow Medical College and Hospital

Results and Publications

Publication and dissemination plan
Planned publication in peer reviewed journal

Intention to publish date
02/02/2026

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication or made available upon request from Asad Khalid, asadkhalid30@gmail.com. The names and IPD numbers of the participants, along with their contact details, will not be shared as the consent form obtained from participants made it clear, and a verbal assurance was given that the personal details of the participants will not be made public under any circumstances.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			07/10/2025	No	No