

**THESIS PROTOCOL**



# **COMPARISON OF INTRAVENOUS MAGNESIUM SULPHATE AND INTRAVENOUS ESMOLOL IN ATTENUATING HEMODYNAMIC STRESS RESPONSE DURING TRACHEAL EXTUBATION**

**Presentation by:**

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**ELMCH**

## **Part A - General Information**

1. **Title of the dissertation:** - Comparison of intravenous Magnesium Sulphate and intravenous Esmolol in attenuating hemodynamic stress response during tracheal extubation

2. **Name of the candidate, mobile number and email:** -

. Name -Dr Asad Khalid

Mobile number- 9452810007

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3. **Month and year of appearing for final examination:** -

May 2023

4. **Name of the course:** -MD Anesthesiology

5. **Year of admission:** -August 2020

6. **Month and year of submitting dissertation:**-December 2022

# **GUIDE**

**Dr. (Prof) SURENDRA SINGH**

Head of Department

Dept. of Anaesthesiology

Era's Lucknow Medical College & Hospital,  
Lucknow.

# **CO-GUIDE**

**Dr. SANNI DEYOL GAUTAM**

Consultant

Dept. of Anaesthesiology

Era's Lucknow Medical College & Hospital,  
Lucknow.

To,

The Principal,

Era's Lucknow Medical College and Hospital,

Lucknow.

Subject: To register Thesis through proper channel

Respected Sir,

I would like to register my thesis titled, **“Comparison of intravenous Magnesium Sulphate and intravenous Esmolol in attenuating hemodynamic stress response during tracheal extubation”** for the **MD ANAESTHESIOLOGY** Examination of ERA UNIVERSITY, Lucknow to be held in year 2023. One copy of protocol is being submitted here with.

Thanking you,

Yours truly,

Dr. Asad Khalid

Place: Era's Lucknow Medical College, Lucknow.

**Forwarded and recommended**

**Dr.(Prof.) Surendra Singh**

**HEAD OF DEPARTMENT (Anaesthesiology)**

Era's Lucknow Medical College &Hospital,

Lucknow.

## **INTRODUCTION**

Tracheal Extubation is an important and integral procedure of general anesthesia.<sup>1</sup> Tracheal Extubation leads to irritation of airways, which may cause cough, leading to an increase in systolic and diastolic blood pressures (SBP & DBP) and also an increase in intrathoracic pressure which can interfere with the cardiac preload.<sup>1,2</sup>

Hypertensive subjects may exhibit an exaggerated response to tracheal extubation compared to normotensives.<sup>1,3,4</sup>

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.<sup>1,5,6</sup>

Esmolol is a short acting, highly cardioselective beta adrenergic receptor antagonist rapidly metabolized by plasma esterase.<sup>1,2,7</sup> The rapid onset of action of esmolol prevents acute increase in heart rate and arterial pressure which occurs at extubation.<sup>1,4,8</sup>

Magnesium is a naturally occurring calcium channel antagonist<sup>1</sup> and non competitive antagonist of N-methyl D-aspartate (NMDA) receptor.<sup>1,3,9</sup> The role of magnesium in blunting the hemodynamic response to endotracheal intubation and extubation is evolving.<sup>1</sup> It has been shown that magnesium inhibits catecholamine release from adrenal medulla and adrenergic nerve endings<sup>10,11</sup>

## **Review of Literature**

1. Dyson A, Isaac PA, Pennant JH, Gieseske AH, Lipton JM.

*Anesth Analg*, 1990; 71: 675-8<sup>8</sup>

### **Esmolol attenuates cardiovascular responses to Extubation.**

Inference- The use of esmolol before extubation may be beneficial in patients with ischemic heart disease and good left ventricular function, especially in the presence of borderline hypertension.

2. Arar C, Colak A, Alagol A, Uzer SS, Ege T et al.

*European Journal of Anaesthesiology* 2007; 24: 826–831<sup>7</sup>

### **The use of esmolol and magnesium to prevent haemodynamic responses to extubation after coronary artery grafting.**

Inference- Esmolol before extubation following coronary artery bypass graft surgery prevents undesirable haemodynamic responses while magnesium reduces undesirable haemodynamic responses but does not prevent them.

3. Goyal S , Shrivastava S. *J. Evol. Med. Dent. Sci.*/eISSN- 2278-4802, pISSN- 2278-4748/  
Vol. 6/ Issue 43/ May 29, 2017 <sup>12</sup>

**Effect of intravenous magnesium sulphate on cardiovascular responses during tracheal extubation in patient undergoing craniotomies.**

Inference- Use of magnesium sulphate before extubation decreases the undesirable cardiovascular responses during extubation period.

4. Agrawal CG, and Khadke SJ. *Indian Journal of Clinical Anaesthesia* 2020; 7(3):457–465 <sup>1</sup>

**Comparison of IV magnesium sulphate and IV esmolol in attenuating hemodynamic extubation response after general anesthesia.**

Inference- Magnesium sulphate provides better hemodynamic stability with postoperative analgesia compared to esmolol when used for attenuating hemodynamic response to extubation.

**RESEARCH QUESTION**

-Which drug between Intravenous Esmolol and Intravenous Magnesium Sulphate is better for attenuating hemodynamic response to Tracheal Extubation ?

**AIM**

-To compare Intravenous Esmolol and Intravenous Magnesium Sulphate in attenuating hemodynamic response to tracheal extubation.

**OBJECTIVES**

This study is intended to –

1. Compare effects of Intravenous Esmolol and Intravenous Magnesium Sulphate in tracheal extubation .
2. Observe the incidence of hemodynamic changes in tracheal extubation.
3. Observe the adverse effects of intravenous Esmolol and intravenous Magnesium Sulphate, if any.

## **SAMPLE SIZE**

### **Sample size at 80% Power of Study**

Sample size is calculated on the basis of percentage fall in heart rate in two groups using the formula

$$n = \frac{(z_{\alpha} + z_{\beta})^2}{[\ln(1-e)]^2} \left[ \frac{1-p_1}{p_1} + \frac{1-p_2}{p_2} \right]$$

Where  $p_1 = 0.2182$  (21.82%) percentage fall in heart rate in first group

$p_2 = 0.3707$  (37.07%) percentage fall in heart rate in second group

(Ref. Chetan Agarwal et. al.)

Proportion ratio  $e = (p_1 / p_2)$  considered to be clinically significant

Type I error,  $\alpha=5\%$  (level of significance)

Type II error  $\beta=20\%$  for setting power of study 80%

The sample size was calculated to be  $n = 40$  in each group.

## **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 .

## **Exclusion Criteria**

1. Patients with 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.

## **MATERIAL AND METHODS**

TYPE OF STUDY: Prospective comparative study

PLACE OF STUDY: Department of Anaesthesiology and Critical Care, Era's Lucknow Medical College and Hospital, Lucknow.

DURATION OF STUDY : 2 years

ETHICAL CLEARANCE : Applied for

### **Methodology**

Written and informed consent shall be taken . Randomised selection of patients planned for surgery under general anesthesia will be done. Patients planned for extubation will be categorised into 2 groups.

- **GROUP A (Esmolol group)** will be administered intravenous Esmolol Infusion with dose 0.5mg/kg diluted in 100 ml normal saline over 10 min started 5 min before extubation.
- **GROUP B (Magnesium Sulphate group)**- will be administered intravenous Magnesium sulphate infusion of dose 40mg/kg diluted in 100 ml normal saline over 10 min started 5 min before extubation.
- First assessment ( $E_B$ ) shall be made 5 minutes before the extubation of patient.
- Second assessment ( $E_0$ ) shall be made at the time of extubation.
- Third assessment ( $E_5$ ) will be done 5 minutes after extubation.
- Fourth assessment ( $E_{10}$ ) will be done 10 minutes after extubation,
- Fifth assessment ( $E_{15}$ ) will be done 15 minutes after extubation

### **PARAMETERS TO BE RECORDED**

- Systolic Blood Pressure (SBP)
- Diastolic Blood Pressure (DBP)
- Mean Arterial Pressure (MAP)
- Heart Rate (HR)



Drug Given	Esmolol		Magnesium Sulphate		
	E <sub>B</sub>	E <sub>0</sub>	E <sub>5</sub>	E <sub>10</sub>	E <sub>15</sub>
Systolic BP(SBP)					
Diastolic BP(DBP)					
Mean Arterial Pressure(MAP)					
Heart Rate(HR)					

### **EXPECTED OUTCOME**

The answer to the research question may be found

Name-	IPD No.	Mobile-
Age & Sex-	Height-	
Investigations-	Weight-	
Hb-	BMI-	
TLC-	ASA-	
DLC-	PT-	
Blood Sugar (Random)-	INR	-
S.Urea-		
S.Creatinine-		
SODIUM		
Potassium		
Chloride.		
S.Bilirubin-	direct	indirect.
SGOT-		
SGPT-		
S.AlkalinePhosphatase-		
ECG-		
Diagnosis -		
Surgical Procedure –		
Time Of Incision-		
Time of Intubation-		
Durationof Surgery-		
Time of Extubation-		

## INFORMED CONSENT FORM

I have been told in detail about the study **“COMPARISON OF IV ESMOLOL AND IV MAGNESIUM SULPHATE IN ATTENUATING HEMODYNAMIC RESPONSE IN EXTUBATION ”** in Era’s Lucknow Medical College & Hospital, Lucknow by Dr .Asad Khalid. Detailed information has been given to me. I have been made aware about the benefits and the side effects related to investigation and administration of these drugs. This study will result in new knowledge that will be beneficial to mankind. In relation to this study all points have been explained to me in detail and I got the opportunity to ask questions and satisfactory answers were provided to me. I willingly give my approval for being a part of this study and I am told that I can opt out of this study anytime without giving any explanation.

Name of patient/guardian

Name Of Investigator

Signature.....

Signature.....

Name of Witness.....

Address.....

.....

Signature.....

ELMCH, LUCKNOW

**INFORMED CONSENT FORM FOR RESEARCH**  
**ERAS LUCKNOW MEDICAL COLLEGE & HOSPITAL, LUCKNOW**  
**(PART 1: INFORMATION SHEET)**

## **INTRODUCTION**

I am Dr. Asad Khalid, MD Resident in Department of Anaesthesiology, Era's Lucknow Medical College & Hospital, Lucknow. The title of my research is "**COMPARISON OF IV ESMOLOL AND IV MAGNESIUM SULPHATE IN ATTENUATING HEMODYNAMIC RESPONSE IN EXTUBATION**". I invite you to be a part of this research. Information will be provided and you are free to decide whether or not you will participate in the research. Before you decide you can talk to anyone you feel comfortable with about the research. There may be some words that you may not understand. Kindly, ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask me.

## **PARTICIPANT SELECTION**

All patients undergoing surgery under General Anaesthesia, who will be extubated at the end of surgery.

## **VOLUNTARY PARTICIPATION**

Your decision to participate in this study is entirely voluntary. If you choose not to consent, all the services you receive at this hospital will continue and nothing will change. You may also choose to change your mind later and stop participating even if you agreed earlier. The services you receive at the hospital will continue.

## **DESCRIPTION OF THE PROCESS**

Randomised selection of patients planned for surgery under general anesthesia will be done. Patients planned for extubation will be categorised into 2 groups.

**GROUP A (Esmolol group)** will be administered intravenous Esmolol Infusion with dose 0.5mg/kg diluted in 100 ml normal saline over 10 min started 5 min before extubation.

**GROUP B (Magnesium Sulphate group)**- will be administered intravenous Magnesium sulphate infusion of dose 40mg/kg diluted in 100 ml normal saline over 10 min started 5 min before extubation.

## **DURATION**

The research will take place over a period of two years.

## **BENEFITS OF THE STUDY**

To compare intravenous esmolol and intravenous magnesium sulphate in attenuating hemodynamic response in extubation

## **CONFIDENTIALITY**

We will not be sharing the identity of those participating in the research and all the information collected will be confidential.

## **RIGHT TO REFUSE OR WITHDRAW**

You do not have to agree to take part in this research if you do not wish to do and it will not affect your treatment at this Centre in anyway.

## **WHOM TO CONTACT**

In case of any queries now or later you can ask any question to me even after the study has started.

If you want to ask questions later, you may contact

**Dr. ASAD KHALID**

Resident MD Anaesthesia

Era's Lucknow Medical College and Hospital Lucknow

Mobile no. 9452810007 Email- asad\_khalid30@yahoo.com

**(Part II: Information Sheet)**

I have read the forgoing information, or it has been read to me. I have the opportunity to ask question about it and any question that I have asked have been answered to my satisfaction.

**I consent voluntarily to participate as participant in this research**

1. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
2. I understand that my identity will not be revealed in any information released to third party published.
3. I agree not to restrict the use data or results that arise from this study provided such a use only for scientific purpose.
4. I have received a copy of signed patients information/informed consent.

**Name of participant:** .....

**Signature of Participant/relative:** .....

**Date:** .....

**If Illiterate:**

I have witnessed the accurate reading of the consent form to potential participant, and the individual has had the opportunity to ask question. I confirm that the individual has given consent freely.

**Name of witness:** .....and thumb print of participant

**Signature of witness:** .....

**Date:** .....

**Statement by researcher/ person taking consent:**

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done.

I confirm that the participant was given an opportunity to ask questions about the study, and the entire questions asked by the participant have been answered correctly and to the best of my ability.

I confirm that the individual has not been forced into giving consent, and the consent has been given freely and voluntarily,. A copy of this information sheet has been provided to the participant.

.....	.....	.....
Name of patient	Signature	Date & Time
.....	.....	.....
Name of StudyDoctor	Signature	Date & Time
.....	.....	.....
Name of witness	Signature	Date & Time

Comments

Signed copy of the patient information sheet provided to the patient.

## **CONSENT FORM**

Department of Anaesthesiology

Era's Lucknow Medical College and Hospital, Lucknow

Study of : **COMPARISON OF IV ESMOLOL AND IV MAGNESIUM SULPHATE IN  
ATTENUATING HEMODYNAMIC RESPONSE IN EXTUBATION**

My patient \_\_\_\_\_ is ready to participate in the above mentioned study and test procedures explained to me. I am told about the consequences involved in the study. I am told that I can withdraw from the study as and when I want to and my personal details will not be made public under any circumstances.

Name/signature of patient/guardian

Name/signature of investigator

Witness(if participant is illiterate)

Date:\_\_\_\_\_



### सूचित सहमति प्रपत्र

- मुझे एरा लखनऊ मेडिकल कॉलेज एंड हॉस्पिटल, लखनऊ में “COMPARISON OF IV ESMOLOL AND IV MAGNESIUM SULPHATE IN ATTENUATING HEMODYNAMIC RESPONSE IN EXTUBATION ” में अध्ययन के बारे में विस्तार से बताया गया है। डॉ। असद खालिद द्वारा इसकी विस्तृत जानकारी मुझे दी गई है। मुझे इन दवाओं की जांच और प्रशासन से संबंधित लाभों और दुष्प्रभावों के बारे में अवगत कराया गया है। इस अध्ययन से नए ज्ञान का परिणाम होगा जो मानव जाति के लिए फायदेमंद होगा। इस अध्ययन के संबंध में मुझे सभी बिंदुओं के बारे में विस्तार से बताया गया है और मुझे प्रश्न पूछने का अवसर मिला और मुझे संतोषजनक उत्तर प्रदान किए गए। मैं स्वेच्छा से इस अध्ययन का हिस्सा बनने के लिए अपनी स्वीकृति देता हूं और मुझे बताया गया है कि मैं बिना कोई स्पष्टीकरण दिए कभी भी इस अध्ययन से बाहर निकल सकता हूं। मेरी व्यक्तिगत जानकारी किसी भी परिस्थिति में सार्वजनिक नहीं की जाएगी।

रोगी / अभिभावक का नाम

अन्वेषक का नाम हस्ताक्षर

.....

.....

हस्ताक्षर .....

साक्षी का नाम .....

पता .....

हस्ताक्षर .....

एलएमसीएच, लखनऊ

## رضامندی فارم

ایرا کے لکھنؤ میڈیکل کالج اینڈ اسپتال ، لکھنؤ میں

### “COMPARISON OF IV ESMOLOL AND IV MAGNESIUM SULPHATE IN ATTENUATING HEMODYNAMIC RESPONSE IN EXTUBATION”

” کے مطالعے کے بارے میں مجھے تفصیل سے بتایا گیا ہے۔ ڈاکٹر۔ اسد خالد۔ تفصیلی معلومات مجھے دی گئی ہیں۔ مجھے ان منشیات کی تحقیقات اور انتظامیہ سے متعلق فوائد اور مضر اثرات کے بارے میں آگاہ کیا گیا ہے۔ اس مطالعے کے نتیجے میں نیا علم حاصل ہوگا جو بنی نوع انسان کے لئے فائدہ مند ہوگا۔ اس مطالعے کے سلسلے میں مجھے تمام نکات تفصیل سے بیان کیے گئے ہیں اور مجھے سوالات پوچھنے کا موقع ملا اور مجھے تسلی بخش جوابات فراہم کیے گئے۔ میں اس مطالعے کا حصہ بننے کے لئے خوشی سے اپنی منظوری دیتا ہوں اور مجھے بتایا جاتا ہے کہ میں بغیر کسی وضاحت کے کسی بھی وقت اس مطالعے سے باہر نکل سکتا ہوں۔ اور میری ذاتی تفصیلات کو کسی بھی صورت میں عام نہیں کیا جائے گا۔

مریض / سرپرست کا نام تفتیش کار کا نام دستخط

..... دستخط .. گواہ کا نام .. پتہ .....  
..... دستخط ..

ایل ایم سی ایچ ، لکھنؤ

## **References**

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