

**COMPARISON OF MAGNESIUM SULPHATE 30 MG/KG WITH  
LIDOCAINE 1,5 MG/KG IN HEMODYNAMIC CHANGES AND  
CORTISOL LEVEL POST INTUBATION IN PATIENT UNDERGOING  
CRANIOTOMY**

**THESIS**



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**PROGRAM PENDIDIKAN DOKTER SPESIALIS  
PROGRAM STUDI ANESTESIOLOGI DAN TERAPI INTENSIF  
FAKULTAS KEDOKTERAN  
UNIVERSITAS SUMATERA UTARA  
MEDAN  
2024**

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LIDOCAINE 1,5 MG/KG IN HEMODYNAMIC CHANGES AND  
CORTISOL LEVEL POST INTUBATION IN PATIENT UNDERGOING  
CRANIOTOMY**

**THESIS**

**Diajukan Sebagai Salah Satu Syarat Untuk Memperoleh Gelar Dokter  
Spesialis Dalam Program Studi Anestesiologi dan Terapi Intensif Pada  
Fakultas Kedokteran Universitas Sumatera Utara**

**Oleh:**

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MEDAN  
2024**

## LEMBAR PENGESAHAN

Judul Tesis :

**PERBANDINGAN PEMBERIAN MAGNESIUM SULFAT 30 MG/KGBB  
DENGAN LIDOKAIN 1,5 MG/KGBB TERHADAP PERUBAHAN  
RESPON HEMODINAMIK DAN KADAR KORTISOL PASKA  
INTUBASI PADA PASIEN YANG MENJALANI  
KRANIOTOMI**

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Telah diuji pada Hari /Tanggal : 8 Januari 2024

Telah diuji pada tanggal: 8 Januari 2024

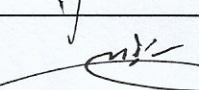
**PANITIA PENGUJI PROPOSAL TESIS**

**TANDA TANGAN**

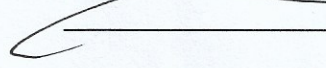
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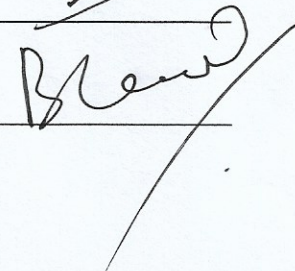
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**PERBANDINGAN PEMBERIAN MAGNESIUM SULFAT  
30 MG/KGBB DENGAN LIDOKAIN 1,5 MG/KGBB TERHADAP  
PERUBAHAN RESPON HEMODINAMIK DAN KADAR KORTISOL  
PASKA INTUBASI PADA PASIEN YANG MENJALANI KRANIOTOMI**

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<sup>1</sup>Program Studi Anestesiologi dan Terapi Intensif, Fakultas Kedokteran,  
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**Abstrak**

**Pendahuluan** Pada kraniotomi, respon stres dapat terjadi dari peningkatan hemodinamik hingga respon stres hormonal seperti meningkatnya kadar kortisol. Intubasi merupakan faktor utama yang harus dipertimbangkan saat induksi neuroanestesi. Intubasi secara endotrakeal merupakan komponen penting dari anestesi umum pada tindakan operasi kraniotomi. Magnesium sulfat memiliki keuntungan dalam hal menjaga kestabilan autoregulasi otak dan neuroprotektif.

**Metode** Magnesium sulfat memiliki keuntungan dalam hal menjaga kestabilan autoregulasi otak dan neuroprotektif. Dengan total sampel minimal untuk seluruh kelompok sebesar 30 sampel yang dibagi menjadi 3 kelompok pasien yang mendapat lidokain, MgSO<sub>4</sub> dan kelompok control yang mendapatkan NaCl

**Hasil** Terdapat perbedaan yang signifikan antara ketiga kelompok dengan hemodinamik dan kadar serum kortisol ditemukan lebih rendah pada kelompok lidokain

**Kesimpulan** Pemberian Lidokain 1,5 mg/kgbb secara intravena paling efektif dalam melemahkan kejadian respon stress berupa peningkatan tekanan darah, HR dan kadar serum kortisol akibat tindakan laringoskopi dan intubasi pada pasien yang menjalani kraniotomi dibandingkan pemberian MgSO<sub>4</sub> 30 mg/kgbb secara intravena

**Kata Kunci** Kraniotomi, Intubasi, Lidokain, MgSO<sub>4</sub>

**Comparison of Magnesium Sulphate 30 mg/KgBW with Lidocaine 1,5 mg/KgBW in Hemodynamic Changes and Cortisol Level post Intubation in Patient Undergoing Craniotomy**

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**Abstract**

**Introduction** In craniotomy, stress responses can occur from increased hemodynamics to hormonal stress responses such as increased cortisol levels. Intubation is a major factor that must be considered during the induction of neuroanesthesia. Endotracheal intubation is an important component of general anesthesia in craniotomy surgery. Magnesium sulfate has advantages in terms of maintaining the stability of brain autoregulation and is neuroprotective.

**Method** Magnesium sulfate has advantages in terms of maintaining the stability of brain autoregulation and is neuroprotective. With a minimum total sample for the entire group of 30 samples which were divided into 3 groups of patients who received lidocaine, MgSO<sub>4</sub> and a control group who received NaCl 0,9%

**Results** There were significant differences between the three groups with hemodynamic and serum cortisol values found to be lower in the lidocaine group

**Conclusion** Intravenous administration of Lidocaine 1.5 mg/kgbb is most effective in attenuating the stress response in the form of increased blood pressure, HR and serum cortisol levels due to laryngoscopy and intubation in patients undergoing craniotomy compared to intravenous administration of MgSO<sub>4</sub> 30 mg/kgbb

**Keywords** Craniotomy, Intubation, Lidocaine, MgSO<sub>4</sub>



## KATA PENGANTAR

Penulis mengucapkan puji dan syukur kehadirat Allah SWT yang telah memberikan berkah-Nya kepada Penulis sehingga dapat menyelesaikan tesis ini. Selama melakukan penelitian dan penulisan tesis, penulisan banyak memperoleh bantuan moril dan materil dari berbagai pihak. Oleh karenanya, pada kesempatan ini penulis menyampaikan ucapan terima kasih yang tulus kepada:

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Penulis menyadari tesis ini masih banyak memiliki kekurangan dan jauh dari sempurna. Namun harapan penulis semoga tesis ini bermanfaat kepada seluruh pembaca. Semoga kiranya Tuhan Yang Maha Esa memberkati kita semua. Amin.

Medan, April 2024

Penulis,

dr. Arsil Radiansyah

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## CHAPTER III

### RESEARCH METHODS

#### 3.1 Research Design

This research design used a double-blind, randomized controlled clinical trial with *pre test post test with control group design*, to assess the comparison of post-intubation hemodynamics and cortisol when administering intravenous Magnesium sulfate and intravenous Lidocaine.

#### 3.2 Place and Time of Research

This research will be carried out at the Central Surgical Installation (IBP) of several hospitals, namely:

1. Adam Malik Haji Central General Hospital Medan (RSUP HAM).
2. Teaching Hospital (RSP) Prof. Dr. Chairuddin Panusunan Lubis.
3. Rumkit Level II Putri Hijau Medan.
4. RSU Haji Medan

This research began to be carried out after its publication *I* from the Health Research Ethics Committee of the University of North Sumatra and a research permit from each hospital.

#### 3.3 Research Population and Sample

The study population was all patients who underwent craniotomy surgery. The sample for this study was all patients undergoing surgery who met the inclusion and exclusion criteria.

#### 3.4 Size of Research Subjects

The formula for determining the sample size used in this research is:

$$n1 = n2 = n3 = 2 \frac{(Z\alpha + Z\beta)s^2}{(x1 - x2)^2}$$

$Z\alpha$  = value on a standard normal distribution equal to level significance of  $\alpha$  (for  $\alpha=0.05$  it is 1.96).

$Z\beta$  = value in the standard normal distribution which is the same as power as large as desired (for  $\beta=0.20$  it is 0.84). *x1*

$x_1 - x_2$  = difference in cortisol levels between groups that is considered significant  
10.4  $\mu\text{g/dl}$

s = standard deviation of cortisol in previous studies 5.85  $\mu\text{g/dl}$

$$\begin{aligned} n_1 &= n_2 = n_3 \\ &= 2 \frac{(1.96 + 0.84)5.8}{10.4^2} \end{aligned}$$

$$n_1 = n_2 = n_3 = 9.04$$

From the results of calculations using the sample size formula above, the sample size for each group is 9.04 samples. Then the sample was added by 10%, obtaining a sample size for each group of 10. So the minimum total sample for the entire group was 30 samples.

### 3.5 Selection of Research Subjects

Research subjects were taken using techniques *consecutive sampling* until the number of research subjects is met. Randomization was carried out by volunteers using a computerized randomization method using a website [www.randomizer.org](http://www.randomizer.org). The three groups were divided into groups A (intravenous magnesium sulfate), B (intravenous lidocaine) and C (control).

### 3.6 Research Criteria

#### 3.6.1 Inclusion Criteria

1. Patients aged 18-65 years
2. Body mass index (BMI) 18.5  $\text{kg/m}^2$ – 29.9  $\text{kg/m}^2$
3. The patient or family agrees to be a research subject

4. Non-traumatic craniotomy cases, namely evacuation of supratentorial brain tumors, evacuation of intracerebral hemorrhage, subdural hemorrhage, cerebrovascular correction.
5. Patients undergoing elective non-traumatic craniotomy surgery at IBP HAM Hospital, RSP Prof. Dr. Chairuddin Panusunan Lubis, Rumkit Tk.II Putri Hijau Medan, and RSU Haji Medan

### 3.6.2 Exclusion Criteria

1. Patients with heart problems.
2. Patients with liver disorders
3. Patients with kidney disorders
4. Patients with pregnancy
5. Patients with hypertension or hypotension before surgery
6. Patients who are known to be hypersensitive to MgSO<sub>4</sub> and/or Lidocaine
7. Patients with chronic use of corticosteroid drugs, *Calcium channel blockers*, The drug contains magnesium and opioids
8. Patients at risk of difficult intubation and ventilation according to the LEMON score and MOANS score criteria
9. Patients with cortisol secretion disorders (pituitary tumors or hypothalamic tumors or adrenal gland disorders)
10. Patients with hypocortisol or hypercortisol on T0 serum cortisol examination

### 3.6.3 Criteria Drop Out

1. Patients with more than 1 intubation and endotracheal intubation time of more than 1 minute
2. The patient dies *intraoperative*.

## 3.7 Research Variables

Independent variables: Magnesium sulfate 30 mg/kgbb, Lidocaine 1.5mg/kgbb and

## Intravenous control:

Dependent variable Hemodynamics and cortisol levels

## 3.9.2 How it Works

1. Patients who have been registered for planned surgery according to the indications of the neurosurgery department who have met the inclusion and exclusion criteria are recruited to become research subjects.
2. Patients are given an explanation of the research procedures and asked to sign an agreement to participate in the research.
3. The sample was divided randomly into 3 groups and double-blind randomization was carried out using an application *randomizer.org*
4. After randomization, they were divided into 3 groups consisting of patients who received MgSO<sub>4</sub> 30 mg/KgBW, Lidocaine 1.5 mg/KgBW and Control
5. The patient is prepared on the operating table in a supine position before induction. The patient is checked for systolic blood pressure, diastolic blood pressure, MAP, pulse and blood cortisol levels (blood sample tubes are given code K0)
6. The first group of patients was given MgSO<sub>4</sub> 30 mg/KgBW diluted in 20 ml with 0.9% NaCl, labeled with code A and administered within 5 minutes with *syringe pump*, The second group was given 1.5 mg/kg Lidocaine diluted in 20 ml with 0.9% NaCl, labeled with code B and given within 5 minutes with a syringe pump, The third group was given 0.9% NaCl, in a 20 ml syringe labeled with code C and given within 5 minutes with a syringe pump. With all three groups of patients receiving maintenance fluids *Ringer Solution*
7. The patient was induced 10 minutes after intervention with:
 

Midazolam	: 0.07 mg/kgBB
Fentanyl	: 2 mcg/kgBB
Propofol	: 2 mg/kgBB
Rocuronium	: 1 mg/kgBB

8. After induction and intubation by PPDS anesthesiology and intensive therapy FK USU semester 5 and above. The patient is then recorded for systolic blood pressure, diastolic blood pressure, MAP, pulse at T1 (3 minutes), T2 (5 minutes), T3 (7 minutes), T4 (10 minutes). At T4 a blood cortisol sample was also taken (the blood sample tube was given the code K1).
9. Then record and analyze the data.
10. If hypertension occurs with  $TDS \geq 150$  mmHg 5 minutes after intubation, administered *calcium channel blockers* (titration starting from 0.25 mg/KgBW/hour *Nicardipine*) or Hypotension with  $TDS \leq 80$  mmHg 5 minutes after intubation given Ephedrine 5-10 mg. If HR bradycardia occurs  $\leq 50$  x/minute give *atropine sulfate* 0.5 mg.

### 3.8 Analysis Plan

After the required data has been collected, the data is then checked again for completeness before being tabulated and processed. Then the data is coded to make it easier to tabulate.

Data is tabulated into a master table using *software SPSS version 21*. Normality test uses Shapiro Wilk, numerical data in mean SD (standard deviation) and median (minimum-maximum) values. Meanwhile, categorical data is displayed in numbers (percentages). The dependent t-test (if the data is not normally distributed, the alternative is the Wilcoxon test) is used to determine the difference in hemodynamic response and cortisol levels before and after intervention in each group, the Anova test (if the data is not normally distributed, the alternative is the Kruskal-Wallis test ) was used to determine differences in hemodynamic responses and cortisol levels in the MgSO group<sup>4</sup>, Lidocaine group and Control group. Statistical analysis uses a 95% confidence interval with a p value  $<0.05$  considered significantly significant.

### 3.9 Research Flow

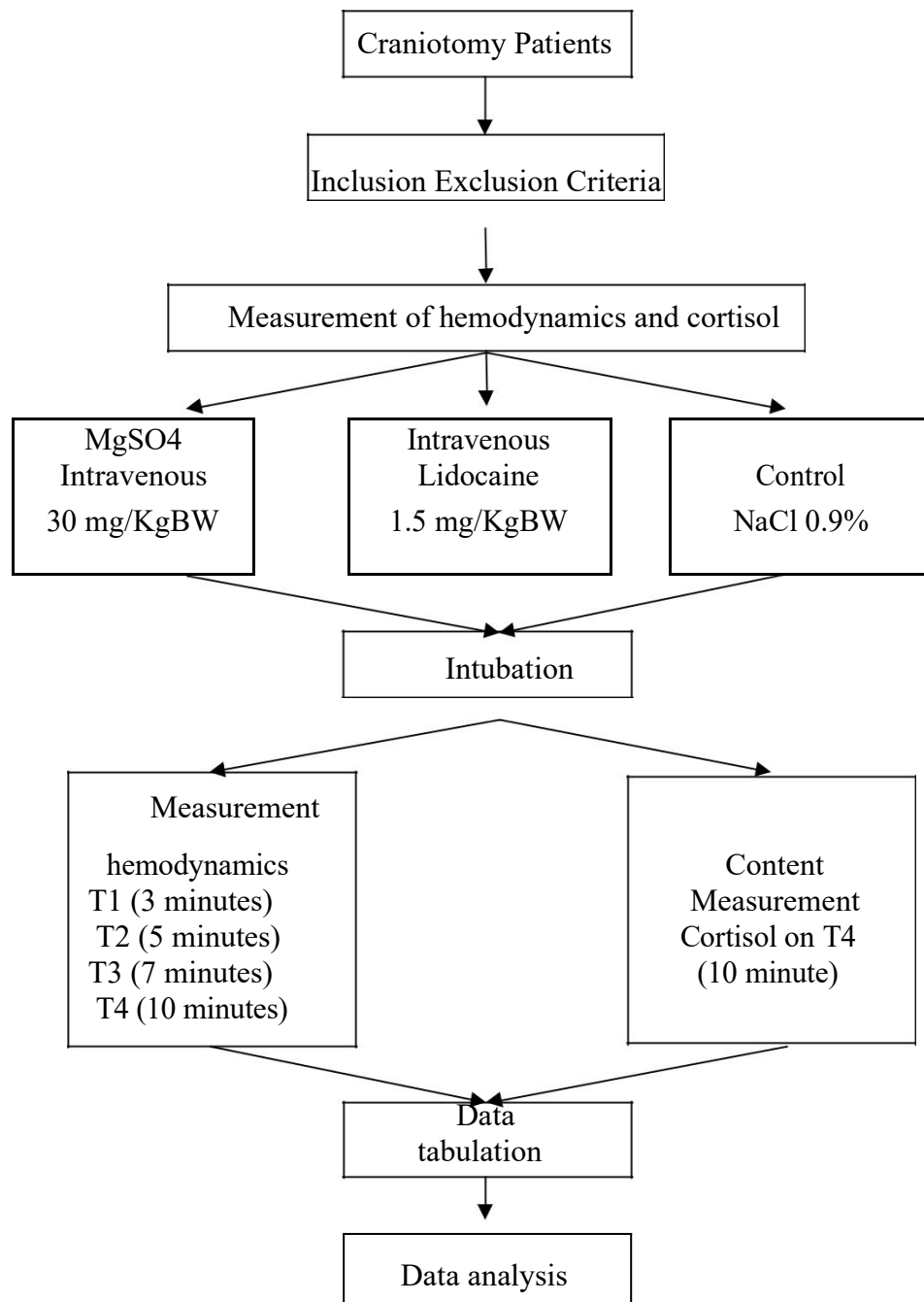


Figure 3.1 Research Flow.



### 3.10 Research Ethics

Research ethics were carried out after obtaining approval from the Health Research Ethics Committee of the University of North Sumatra and Haji Adam Malik Hospital Medan, Prof. Dr. Chairuddin Panusunan Lubis, and Rumkit Tk.II Putri Hijau Medan and RSU Haji Medan. The patient and the patient's family receive an explanation of the procedure to be undertaken, and state their willingness in writing on a sheet *informed consent*

Appendix 2



Name :

Birthdate

MINISTRY OF HEALTH

DIRECTORATE GENERAL OF HEALTH SERVICES DEVELOPMENT

H. ADAM MALIK CENTRAL GENERAL HOSPITAL

Jl. Bunga Lau No. 17 Medan Tuntungan Km.12 Post Box 246 Tel. (061)

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MEDAN-20136

RM.2.11/IC.SPenelitian/2023

EXPLANATION SHEET

RESEARCH TITLE:

COMPARISON OF ADMINISTRATION OF MAGNESIUM SULFATE  
30 MG/KGBB WITH LIDOCAINE 1.5 MG/KGBB ON CHANGES IN HEMODYNAMIC  
RESPONSE AND POST-INTUBATION CORTISOL LEVELS IN PATIENTS UNDERGOING  
CRANIOTOMY

IMPLEMENTING INSTANCE/SMF:

SMF ANESTHESIOLOGY AND INTENSIVE THERAPY FK USU

Dear sir or madam .....

First, we would like to introduce ourselves, the name is Dr. Arsil Radiansyah  
and the team in charge of the Anesthesiology and Intensive Therapy Specialist  
Medical Education Program, Faculty of Medicine, University of North Sumatra,  
we would like to convey to you that we intend to conduct research on  
"University of North Sumatra and are currently conducting research entitled:

"COMPARISON OF ADMINISTRATION OF MAGNESIUM  
SULFATE 30 MG/ KGBB WITH LIDOCAINE 1.5 MG/KGBB ON  
CHANGES IN HEMODYNAMIC RESPONSES AND POST-  
INTUBATION CORTISOL LEVELS IN PATIENTS THOSE  
UNDERGOING CRANIOTOMY."

Endotracheal intubation or placement of a breathing tube has been proven to be a reliable method for securing the airway and is the standard technique for Airway management during neurosurgical surgery. Installation of a breathing tube stimulates hemodynamic effects and a stress response which can have negative effects on organs especially the brain and heart. Attenuation of the response to painful stimuli during the installation of a breathing tube can have a beneficial effect on organ function, especially on the cerebrovascular system before neurosurgical surgery. This research concerns services in the operating room for craniotomy surgery patients with GA-ETT anesthesia afterwards so they need drugs that help to reduce the occurrence of stress responses and hemodynamic changes

This study is expected to assess the comparison of administration of magnesium sulfate with lidocaine on the hemodynamic response and changes in serum cortisol as an indicator of the stress response due to post-intubation pain in craniotomy surgery patients. The research procedures to be carried out are as follows:

1. The patient underwent craniotomy under general anesthesia and underwent examination and consent.
2. After the patient arrives in the operating room, the patient is prepared on the operating table in a supine position before induction. The patient is checked for blood cortisol levels and hemodynamics are recorded.
3. The first group of patients was given **MgSO4 30 mg/KgBW** which in dilute in 20 ml with 0.9% NaCl and give within 5 minutes with a syringe pump. The second group is given **lidocaine 1.5 mg/kgBW**

which is diluted in 20 ml with 0.9% NaCl and given in 5 minutes with a syring pump. The third group was given 0.9% NaCl, in a 20 ml syringe and given within 5 minutes with a syring pump. With all three groups of patients receiving Ringer Solution maintenance fluid

4. After induction and intubation. The patient then recording is carried out at T1 (3 minutes), T2 (5 minutes), T3 (7 minutes), T4 (10 minutes) hemodynamics. At T4 it is also carried out cortisol sampling blood.
5. This assessment was carried out directly by researchers who were not involved in administering medication to the patient.

In this study there are no side effects and the confidentiality of your data will be maintained properly. Patients have the right to refuse to participate in research and have the right to withdraw from research. All funding is borne by researchers.

Your participation in this research is voluntary and without coercion and you can withdraw at any time. and for my thanks to sir/madam I

will give gifts in the form of food and drinks. Not occur changes in the quality of service from doctors to you if you are not willing to take part in this research. You will continue to receive routine standard health services in accordance with health service procedures.

If you are willing, then we expect you to sign the Consent After Explanation (PSP) sheet. If you have any complaints during treatment, you can contact me on (085261274162). Researchers will try to help resolve your complaints. That's what we can say. We thank you for your attention and cooperation.

Medan, 2024

Researcher

(Dr. Arsil Radiansyah)

# Appendix 3



RM.2.11/IC.SPenelitian/2022NRM :

Name :

Gender:

Date. Born :



H. Adam Malik Hospital- USU FK

RESEARCH CONSENT FORM (INFORMED CONSENT FORM)			
Principal Researcher		: Dr. Arsil Radiansyah	
Information Provider		:	
Information Recipient		:	
Subject Name		:	
Date of Birth (age)		:	
Gender		:	
Address		:	
No. Tel (Cell)		:	
TYPE OF INFORMATION		INFORMATION CONTENT	MARK
1	Research Title	“COMPARISON OF ADMINISTRATION OF MAGNESIUM SULFATE 30 MG/KGBB WITH LIDOCAINE 1.5 MG/KGBB ON CHANGES IN RESPONSE HEMODYNAMICS AND LEVELS POST-INTUBATION CORTISOL IN UNDERSTANDING PATIENTS CRANIOTOMY”	
2	Objective study	To analyze the comparison of administering magnesium sulfate 30 mg/kgBW with lidocaine 1.5 mg/KgBW on changes in hemodynamic response and post-intubation cortisol levels in patients undergoing craniotomy	
3	Method &	According to research procedures	

	Procedure Study		
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4	Number of Subjects	30 Research subjects	
5	Time Study	February 2024 until the sample size is reached	
6	Benefit study including benefits for subject	a) improve the quality of service to the community, especially to patients undergoing craniotomy. b) The results of this research can be used in determining therapeutic options <i>cost effective</i> for post-craniotomy patients.	
7	Risks & effect side in study	In general, this research will not cause anything dangerous for you.	
8	No comfort subject study	This study does not cause discomfort to the patient	
9	Protection Subject <i>Prone to</i>	Consent to the research is carried out by the witness/guardian if the subject cannot read and write, has decreased consciousness, has a mental disorder and is under 18 years of age.	
10	Compensation when an effect occurs side	If anything undesirable happens during the research, which is caused by the treatment carried out in this research, you can contact me, Dr. Arsil Rahadiansyh (tel: 085261274162). All costs incurred for this research and the consequences arising from this research are the full responsibility of the Research Supervisor and myself as the researcher. The research will be supervised and supervised by expert doctors in the Anesthesiology and Intensive Medical Therapy section of the University of North Sumatra.	
11	Alternati ve Handling if there	-	

12	Guarding Confidentiality Data	All your data will be kept confidential regarding the results of this research. The data we take is the result of our research and related research variables	

13	Costs are borne by researcher	All related costs outside normal procedures will be borne by the researcher, research costs are attached	
14	Incentives for subject	Food and drink parcels	

After listening to the explanation on pages 1 and 2 regarding the research to be carried out by: dr. Arsil Radiansyah, I have understood this information well.

By signing this form I agree, I/..... to be included in the above research voluntarily without coercion from any party. If at any time I feel disadvantaged in any form, I have the right to cancel this agreement.



Subject's Guardian's Signature or Thumbprint

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-Name and Signature of Subject Guardian

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-- - Researcher's Signature

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Name of Researcher

## Appendix 4

### CONSENT SHEET AFTER EXPLANATION (INFORMED CONSENT)

I, the undersigned, are:

Name :

Place and date of birth ;

Age/Gender : Age/Male/female

Address :

Phone number ;

Based on previous explanations from researchers, namely dr. Arsil Radiansyah, I have received very clear information regarding research regarding "COMPARISON OF ADMINISTRATION OF 30 MG/KGBB MAGNESIUM SULFATE WITH 1.5 MG/KGBB LIDOCAINE ON CHANGES IN HEMODYNAMIC RESPONSE AND POST-INTUBATION CORTISOL LEVELS IN PATIENTS UNDERGOING CRANIOTOMY". Therefore, I am hereby willing to become an informant as part of this research, this research voluntarily and without coercion and can resign at any time without any sanctions.

Medan, 2024

Researcher

Respondent

(Dr. Arsil Radiansyah)

( )

Witness

( )