

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Hemodynamic changes due to endotracheal intubation in severe preeclamptic patients during cesarean section with General Anesthesia

Protocol summary

Summary

The pressor response to laryngoscopy is known to be exaggerated in patients with severe preeclampsia. The aim of the study is to compare the effects of intravenous Labetalol or remifentanyl on cardiovascular responses to tracheal intubation. Following approval from the Local Ethics Committee and receipt of written informed consent, 70 preeclamptic parturients undergoing cesarean section with general anesthesia will be randomly assigned in two groups. Group 1, will receive intravenous remifentanyl 1µg/kg two min prior to induction of anesthesia (n=35), and group 2 will receive intravenous labetalol 0.25 mg/kg (n=35) before rapid sequence induction of anesthesia using thiopental 5 mg/kg and suxamethonium 1.5 mg/kg. Systolic, diastolic and mean arterial pressure, heart rate, and any type of arrhythmias will be recorded and compared between two groups at pre-induction, pre-intubation, and at 1, 3, and 5 min after intubation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014022810765N5**

Registration date: **2014-07-25, 1393/05/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-07-25, 1393/05/03

Registrant information

Name

Sousan Rasooli

Name of organization / entity

Alzahra hospital/Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1553 9161

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-07-02, 1393/04/11

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Hemodynamic changes due to endotracheal intubation in severe preeclamptic patients during cesarean section with General Anesthesia

Public title

Comparison of hemodynamic changes due to endotracheal intubation with labetalol and remifentanyl in severe preeclamptic patients undergoing cesarean delivery with General Anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : parturients with severe preeclampsia undergoing cesarean section with general anesthesia; women with ASA class II and III; patient's written informed consent for contribute in study Exclusion criteria: Women with ASA class IV or above; patients with severe asthma; congestive heart failure; arrhythmia;

problems with intubation

Age
From **19 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for research, Tabriz University of Medical Sciences

Street address

Tabriz university of Medical Sciences

City

Tabriz

Postal code

Approval date

2014-07-01, 1393/04/10

Ethics committee reference number

9353

Health conditions studied

1

Description of health condition studied

complication of anesthesia

ICD-10 code

0.29-8

ICD-10 code description

Primary outcomes

1

Description

Blood Pressure

Timepoint

Pre-induction, pre-intubation, and at 1, 3, and 5 min after intubation

Method of measurement

None Invasie BP measure

Secondary outcomes

1

Description

Heart Rate

Timepoint

Pre-induction, pre-intubation, and at 1, 3, and 5 min after intubation

Method of measurement

ECG Monitoring

Intervention groups

1

Description

Patients in group 1 will be received remifentanyl 1µg/kg intravenously 2 minute prior to induction of anesthesia. Then rapid sequence induction of anesthesia using thiopental 5 mg/kg and suxamethonium 1.5 mg/kg will perform.

Category

Treatment - Drugs

2

Description

Patients in group 2 will be received labetalol 0.25 mg/kg intravenously 5 minute prior to induction of anesthesia. Then rapid sequence induction of anesthesia using thiopental 5 mg/kg and suxamethonium 1.5 mg/kg will perform.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr. Sousan Rasooli

Street address

Alzahra Hospital, South Artesh Ave, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Sousan Rasooli

Street addressTabriz University of Medical Sciences, Golgasht Ave,
Tabriz**City**

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Sousan Rasouli

Position

Associate Professor of Anesthesiology

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Associate Professors of Anesthesiology

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Person responsible for updating data**Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty