

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Tranexamic acid and Intra-abdominal Pressure on Intraoperative Blood Loss in Lumbar Laminectomy

Protocol summary

Summary

This study will be performed as a double blind randomized clinical trial in candidates of lumbar laminectomy aged 15 to 65 years old. The study aimed to evaluate the effect of tranexamic acid and intra-abdominal pressure on intra-operative bleeding. 102 Patients will be allocated to TXA and Placebo groups with random block method. Exclusion criteria include history of renal, hepatic, and cardiac diseases, impaired PT and PTT, aspirin usage in previous two weeks, taking OCP, history of CVA, hypertension, morbid obesity. Intra-abdominal pressure in supine and prone position will be measured after induction of anesthesia. Before incision tranexamic acid 10mg/kg and normal saline 0.1ml/kg will be administered to TXA and Placebo groups consecutively. Then tranexamic acid 1mg/kg/h and normal saline 0.1ml/kg/h in similar syringes infused up to the end of procedure. Lab tests including PT, PTT, Hb, Hct., will be done before and after the procedure. Bleeding will be measured during the operation in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138708021388N1**

Registration date: **2009-01-23, 1387/11/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-01-23, 1387/11/04

Registrant information

Name

anoush dehnadi moghadam

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1727 0456

Email address

dehnadi@gtrc.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research, Guilan University of Medical Sciences

Expected recruitment start date

2008-12-21, 1387/10/01

Expected recruitment end date

2009-06-20, 1388/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Tranexamic acid and Intra-abdominal Pressure on Intraoperative Blood Loss in Lumbar Laminectomy

Public title

The Effect of Tranexamic acid and Intra-abdominal Pressure on Intraoperative Blood Loss in Lumbar Laminectomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: candidates for elective lumbar laminectomy aged between 15 up to 65. Exclusion criteria: history of renal, hepatic, and cardiac diseases, impaired PT and PTT, aspirin usage in previous two

weeks, taking OCP, history of CVA, hypertension, morbid obesity.

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date

2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of the vice chancellor for research

Street address

Namjoo st., Shahid Siadati alley, Building of Research affairs, Guilan University of Medical Sciences

City

Rasht

Postal code

41446-65385

Approval date

empty

Ethics committee reference number

p/2007/132/3

Health conditions studied

1

Description of health condition studied

bleeding during lumbar laminectomy

ICD-10 code

T81.0

ICD-10 code description

T81.0

Primary outcomes

1

Description

mean volume of bleeding

Timepoint

all the time of operation

Method of measurement

to measure the volume of suctioned blood and weigh the collected gauze from the field

2

Description

mean intra-abdominal pressure

Timepoint

before the incision in supine position and after pronation

Method of measurement

to measure intra-vesical pressure by Foley catheter and CVP ruler

3

Description

mean of MAPs during the operation

Timepoint

every 5 minutes

Method of measurement

digital NIBP

Secondary outcomes

1

Description

mean volume of bleeding according to operated segments

Timepoint

all the time of operation

Method of measurement

to measure the suctioned blood and weigh the collected gauze from the field

Intervention groups

1

Description

injection of normal saline 0.1ml/kg before the incision and then 0.1ml/kg/h

Category

Placebo

2

Description

injection of tranexamic acid 10mg/kg before the incision and then 1mg/kg/h

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina Hospital,Trauma Research Center

Full name of responsible person

Dr.Anoush Dehnadi Moghadam

Street address

Bolvare Guilan, 177 st., No:92

City

Rasht

Other areas of specialty/work

Street address

Poursina Hospital, Trauma Research Center

City

Rasht

Postal code

41937-13191

Phone

+98 13 1323 8373

Fax

+98 13 1323 8373

Email

info@gtrc.ir

Web page address

www.gtrc.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for reaserch , Guilan University of Medical Sciences

Full name of responsible person

Dr.Sobhani

Street address

Namjoo st., Shahid Siadati alley, Building of Research Affairs, Guilan University of Medical Sciences

City

Rasht

Grant name

Grant code / Reference number

p/2007/132/3

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-Chancellor for reaserch , Guilan 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

Person responsible for general inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr.Anoush Dehnadi Moghadam

Position

Assistant Professor of Anesthesiology, Fellowship in ICM

Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr.Anoush Dehnadi Moghadam

Position

Assistant Professor of Anesthesiology, Fellowship in ICM

Other areas of specialty/work

Street address

Poursina Hospital,Trauma Research Center

City

Rasht

Postal code

41937-13191

Phone

+98 13 1323 8373

Fax

+98 13 1323 8373

Email

dehnadi@gtrc.ir

Web page address

www.gtrc.ir

Person responsible for updating data

Contact

Name of organization / entity

Guilan university of medical sciences

Full name of responsible person

Dr.Anoush Dehnadi Moghadam

Position

Assistant Professor of Anesthesiology, Fellowship in ICM

Other areas of specialty/work

Street address

Poursina Hospital,Trauma Reaserch Center

City

Rasht

Postal code

41937-13191

Phone

+98 13 1323 8373

Fax

+98 13 1323 8373

Email

dehnadi@gtrc.ir

Web page address

www.gtrc.ir

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