

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of sciatic nerve press for acute post operative pain control in middle ear surgery

Protocol summary

Summary

Objectives: The aim of the study is, assessment of sciatic nerve press for acute post operative pain control in middle ear surgery. In order to evaluation of this effect we prepared a proposal to study this effect for post operative pain management. Design: 100 patients with Tympanoplasty were included. Inclusion criteria was: 20-60 ages with ASA class I-II and exclusion criteria: Addition; Psychopathic disorder; Patient avoidance; previous painful disease and problem on prone positioning. One hour after full recovery and awareness primary pain intensity were measured and recorded by VAS scale. Patients were randomized in to two equal groups (Table of random numbers). Intervention group switched to prone position and according to the size of patients sciatic nerve pressed applied by 11-20 Kg parallel on both posterior part of thigh, for 2 minutes. Then patient turn to rest and supine position and pain score measured every 2hour until 8 hour. If VAS scales elevated more than 4, intravenous Paracetamol infusion started for pain relief and total 8 hour need calculated and recorded. In sham group after prone positioning, technician put his hands over the sciatic nerve parallel on both posterior part of thigh without any pressure (placebo effect). Anesthesia and other medication were similar in both groups. If patients need more Paracetamol for pain relief (pain scores over 4) they got additional dose of Paracetamol. This process was repeated every 2 hour until 6 hours for each group. Outcome: finally pain intensity and analgesic consumption in both group Calculated then compared

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504051772N18**

Registration date: **2015-10-24, 1394/08/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-10-24, 1394/08/02

Registrant information

Name

Dawood Aghamohammadi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1381 8940

Email address

aghamohammadid@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Faculty of Medicine, Tabriz University of Medical Sciences

Expected recruitment start date

2014-11-21, 1393/08/30

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of sciatic nerve press for acute post operative pain control in middle ear surgery

Public title

Assessment of sciatic nerve press for acute post operative pain control in middle ear surgery

Purpose

Supportive

Inclusion/Exclusion criteria
 Inclusion criteria: age: 20-60 ; ASA - II Exclusion criteria:
 Addiction; psychopathic; patient avoidance; previous
 painful disorders; problem on pron positioning

Age
 From **20 years** old to **60 years** old

Gender
 Both

Phase
 3

Groups that have been masked
No information

Sample size
 Target sample size: **100**

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

Ethics committee of Tabriz University of Medical
 Sciences University of Medical Sciences

Street address

Vice Chancellor for Research-Tabriz University of
 Medical Sciences- Daneshgah Street Tabriz East
 Azarbaijan

City

Tabriz

Postal code

Approval date

2013-11-18, 1392/08/27

Ethics committee reference number

344/94

Health conditions studied

1

Description of health condition studied

post operative pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

pain

Timepoint

0-1-2-3-4-5-6-7-8 time of mesurments

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Intravenous Paracetamol as an analgesic consumption

Timepoint

0-1-2-3-4-5-6-7-8 time of mesurments

Method of measurement

Intravenous Paracetamol Dose

Intervention groups

1

Description

Applying pressure on sciatic nerve

Category

Prevention

2

Description

Without applying pressure on sciatic nerve

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital/Tabriz

Full name of responsible person

Dawood Aghamohammadi

Street address

Daneshgah street, Imam Reza Hospital

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Faculty of
 Medicine, Tabriz University of Medical Sciences

Full name of responsible person

Hassan Soleimanpour

Street address

Vice Chancellor for Research-Tabriz University of
Medical Sciences- Daneshgah Street Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Faculty of Medicine, 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

Person responsible for general inquiries

Contact

Name of organization / entity

Anesthesiology Dept, Faculty of Medicine, Tabriz
University of Medical Science

Full name of responsible person

Dawood Aghamohammadi

Position

Associate Professor

Other areas of specialty/work

Street address

Anesthesiology Dept, Faculty of Medicine, Tabriz
University of Medical Science Tabriz

City

Tabriz

Postal code

Phone

+98 41 3381 8940

Fax

Email

aghamohammadid@tbzmed.ac.ir

Web page address

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Anesthesiology Dept, Faculty of Medicine, Tabriz
University of Medical Science

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Person responsible for updating data

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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