

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of the Valsalva Maneuver on Needle Projection Pain and Hemodynamic Responses During Spinal Puncture

Protocol summary

Summary

Objective: To evaluate the effect of Valsalva maneuver on needle projection pain and hemodynamic responses associated with spinal puncture. Design: Randomized clinical trial. Setting: Operating room. Participants: Ninety adults, ASA physical status I and II, undergoing elective surgeries under spinal anesthesia. Interventions: A total of ninety adult patients were randomized into three equal groups. Group I (C): control; Group II (B): pressed a rubber ball (attention-diverting method); Group III (V): blew into sphygmomanometer tubing and hold the mercury column up to 30 mm Hg for a period of at least 20s. Measurements: Spinal needle projection pain was graded using numeric rating scale (NRS): 1-10, where scales of 1-3 were rated as mild, 4-6 as moderate, and > 6 as severe. Blood pressure and heart rate were also recorded five minutes before, during and one and third minutes after spinal puncture.

General information

Acronym

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IRCT registration information

IRCT registration number: **IRCT201011285264N2**
Registration date: **2011-01-31, 1389/11/11**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-01-31, 1389/11/11

Registrant information

Name

Sussan Soltani Mohammadi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences

Expected recruitment start date

2010-01-01, 1388/10/11

Expected recruitment end date

2010-03-30, 1389/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of the Valsalva Maneuver on Needle Projection Pain and Hemodynamic Responses During Spinal Puncture

Public title

Efficacy of the Valsalva Maneuver on Needle Projection Pain and Hemodynamic Responses During Spinal Puncture, a randomized clinical trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients, either sex with ASA physical status I and II, scheduled for elective surgeries under spinal anesthesia. Exclusion criteria: 1) Patients having problems in communication 2) any contraindications to spinal anesthesia 3) Patients who could not hold the mercury column up to 30 mm Hg for a period of at least 20s 4) patients whose spinal puncture could not be

performed in the first attempt.

Age

From **19 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran university of medical sciences, Poorsina street, Keshavarz Avenue

City

Tehran

Postal code

1411713135

Approval date

2009-12-20, 1388/09/29

Ethics committee reference number

389

Health conditions studied**1****Description of health condition studied**

spinal needle projection pain

ICD-10 code

Z41

ICD-10 code description

Procedures for purposes other than remedying health state

Primary outcomes**1****Description**

pain

Timepoint

degree of pain after valsalva maneuver

Method of measurement

numeric rating scale

Secondary outcomes**1****Description**

hemodynamic responses

Timepoint

5 minute before, during and 1 and 3 minute after intervention

Method of measurement

heart rate and blood pressure

Intervention groups**1****Description**

Group II (B): Ball; pressed a rubber ball for diversion of patients attention (attention-diverting method)

Category

Other

2**Description**

Group III (V): Valsalva; blew into sphygmomanometer tubing and hold the mercury column up to 30 mm Hg for a period of at least 20s.

Category

Other

3**Description**

Group I (C): Control (no intervention)

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dr shariati hospital

Full name of responsible person

Sussan Soltani Mohammadi

Street address

North Kargar street, Ale-Ahmad highway

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran university of medical sciences

Full name of responsible person

Dr Shahin Akhoondzadeh

Street address

Keshavarz avenue, Poorsina street

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Tehran

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

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Sussan Soltani Mohammadi

Position

assistant professor

Other areas of specialty/work**Street address**

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Sussan Soltani Mohammadi

Position**Other areas of specialty/work****Street address****City****Postal code****Phone****Fax****Email****Web page address**

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