

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

--

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)

Phone

+98 21 2229 5296

Email address

soltanmo@sina.tums.ac.ir

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

City

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**

Department of Anesthesiology, Dr Ali Shariati
Hospital, North Kargar street, Ale-Ahmad highway,
Tehran

City

Tehran

Postal code

1411713135

Phone

+98 21 2229 5296

Fax

+98 21 8863 3039

Email

soltanmo@sina.tums.ac.ir , soltanmo@gmail.com

Web page address

Person responsible for scientific 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**

Department of Anesthesiology, Dr Ali Shariati
Hospital, North Kargar street, Ale-Ahmad highway

City

Tehran

Postal code

1411713135

Phone

+98 21 2229 5296

Fax

+98 21 8863 3039

Email

soltanmo@sina.tums.ac.ir , soltanmo@gmail.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity****Full name of responsible person**

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