

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Evaluation of Intranasal oxytocine spray effect on preventing post-dural puncture headache after elective cesarean section, A Clinical trial

Protocol summary

Study aim

Determining the effectiveness of nasal oxytocin on the prevention of post-dural puncture headache in women undergoing cesarean section

Design

2 Parallel groups with control group, double-blind, phase 3 on 170 patients, For randomization, the Random allocation software will be used.

Settings and conduct

1. The study will be performed in Kamali Hospital. Women who are candidates for elective cesarean section are admitted according to the inclusion criteria. 2. Exclusion of patients with exclusion criteria in pre-surgery visit by examination. 3. 170 women will be selected and They will be randomly divided into two groups. 5. Administration of 3 puffs (30IU) of nasal oxytocin to intervention group immediately after delivery, as a single dose and a dose of equal volume of normal saline, to the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Elective cesarean section candidates,
Exclusion criteria: Known allergy to any of the studied drugs, Hepatic, renal, cardiac dysfunction, Severe obesity (BMI more than 35), Neuromuscular disease, History of lumbar discopathy / history of neuropathy, opioids or analgesic usage 3 days before the study, Consumption of calcium channel blockers,

Intervention groups

Intervention group: Receiving of 3 puffs (30IU) Nasal oxytocin (alborz drug company, made in Iran) Immediately after delivery
Control group: Receiving of 3 puffs Nasal saline Immediately after delivery

Main outcome variables

The severity of headache after spinal anesthesia

General information

Reason for update

Add the actual recruitment date

Acronym

IRCT registration information

IRCT registration number: **IRCT20201215049725N1**
Registration date: **2021-09-10, 1400/06/19**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-17, 1401/05/26**

Update count: **1**

Registration date

2021-09-10, 1400/06/19

Registrant information

Name

Saeed Hassanigelsefid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3275 5840

Email address

saeedhasani1372@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-29, 1400/07/07

Expected recruitment end date

2021-10-13, 1400/07/21

Actual recruitment start date

2021-05-23, 1400/03/02

Actual recruitment end date

2021-09-15, 1400/06/24

Trial completion date

2021-09-18, 1400/06/27

Scientific title

Evaluation of Intranasal oxytocine spray effect on preventing post-dural puncture headache after elective cesarean section, A Clinical trial

Public title

Evaluation of Intranasal oxytocine spray effect on preventing post-dural puncture headache after cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Elective cesarean candidates

Exclusion criteria:

Allergies to drugs used in this study
BMI more than 35
Hepatic, renal or cardiac disorder
Neuromuscular disease
History of lumbar discopathy / history of neuropathy
Opioids or analgesic usage 3 days before the study
Consumption of calcium channel blockers

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **170**

Actual sample size reached: **170**

Randomization (investigator's opinion)

Randomized

Randomization description

A randomized list will be generated using block randomization method with non-identical blocks of 2, 4 and 6 in two groups. This list will be generated by the following web address:
<https://www.sealedenvelope.com/simple-randomiser/v1/lits>

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding, placebo will be used in the control group which has exact similar appearance with the medicine used in the intervention group. The physician who assess the outcome will not be aware of the patient's groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical

Sciences

Street address

Unit. 5, No. 32, 20 metri resalat Ave, South Kuye Karmandan town, Karaj

City

Karaj

Province

Alborz

Postal code

3133746472

Approval date

2021-05-18, 1400/02/28

Ethics committee reference number

IR.ABZUMS.REC.1400.047

Health conditions studied

1

Description of health condition studied

post-dural puncture headache

ICD-10 code

O89.4

ICD-10 code description

Spinal and epidural anesthesia-induced headache during the puerperium

Primary outcomes

1

Description

headache severity after spinal anesthesia based on vas-score

Timepoint

12, 24, 48, 72 hours after cesarean section

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After cesarean section, The intervention group is given 3-puff (30IU) nasal oxytocin (Alborz Drug Company, Made in Iran) as a single dose immediately after delivery.

Category

Prevention

2

Description

Control group: After cesarean section, The Control group is given 3-puff nasal saline, which its appearance is exactly similar to oxytocin, as a single dose immediately after delivery.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali Hospital

Full name of responsible person

Masoumeh Farahani

Street address

Kamali Hospital, Kamali St., Shohada Sq., Beheshti St.,

City

Karaj

Province

Alborz

Postal code

3134877179

Phone

+98 26 3222 3021

Fax

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Email

Kamali@abzums.ac.ir

Web page address

<https://kamali.abzums.ac.ir/en-us/kamali.abzums.ac/9583/page/%D8%B5%D9%81%D8%AD%D9%87-%D8%A7%D8%B5%D9%84%DB%8C>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Hatam Goodini

Street address

Administrative town., North Taleghani Blvd., Taleghani Sq

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Web page address

<https://www.abzums.ac.ir/fa-IR/DouranPortal/1/page/%D8%B5%D9%81%D8%AD%D9%87-%D8%A7%D8%B5%D9%84%DB%8C>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Banafshe Mashak

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Kamali Hospital, Kamali St., Shohada Sq., Beheshti St.,

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Banafshe Mashak

Position

Assistant Professor

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Saeed Hassanigelsefid
Position
Medicine Intern
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
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Karmandan Town
City
Karaj
Province

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable