Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 pucture 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 Controll 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/lists
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
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Fax
+98 26 3220 4975
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
City
Karaj
Province
Alborz
Postal code
3149779453
Phone
+98 26 3419 7000
Fax
+98 26 3256 3325
Email
Education@abzums.ac.ir
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
Street address
Kamali Hospital, Kamali St., Shohada Sq., Beheshti St.,
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
Banafshe Mashak
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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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
Unit 5, No. 32, 20 meteri Resalat Ave, South Kuye Karmandan Town
City
Karaj
Province
Alborz
Postal code
3133746472
Phone
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Fax
Email
saeedhasani1372@gmail.com

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