Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparison the effect of oral Gabapentin and oral ondansetron and oral Ginger to prevention nausea and vomiting after cesarean section by spinal anesthesia

Protocol summary

Summary

Aim of research is Comparison the effect of oral Gabapentin and oral ondansetron and oral Ginger to prevention nausea and vomiting after cesarean section by spinal anesthesia. The method of research is randomized double blind placebo controlled clinical trial. Study population are pregnant women who come to Arak Taleghani Hospital for elective cesarean section . Inclusion criteria: age18-45; candidate for elective cesarean section by spinal anesthesia.Exclusion criteria: Motion Sickness: sensitivity to Gabapentin and ondansetron and l Ginger;trial more than 2 times for spinal anesthesia.208 women randomly divided in 4 groups(intervention and control). One group (52 person) received capsule Gabapentin 300 mg.Second group (52 person)receive capsule ondansetron 8 mg .Third group receive capsule ginger 1 g.Forth group receive capsule placebo.Before intervention and 1,2,4,6 hour after intervention measure nausea and vomiting.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201401014686N10**
Registration date: **2014-01-03, 1392/10/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-01-03, 1392/10/13

Registrant information

Name

Mehri Jamilian

Name of organization / entity

School of Medicine, Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences ,vice president of education and research

Expected recruitment start date

2013-12-24, 1392/10/03

Expected recruitment end date

2014-05-24, 1393/03/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of oral Gabapentin and oral ondansetron and oral Ginger to prevention nausea and vomiting after cesarean section by spinal anesthesia

Public title

Comparison the effect of oral Gabapentin and oral ondansetron and oral Ginger to prevention nausea and vomiting after cesarean section by spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age18-45; candidate for elective cesarean section by spinal anesthesia. Exclusion criteria:

Motion Sickness: sensitivity to Gabapentin and ondansetron and Ginger;trial more than 2 times for spinal anesthesia.

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **208**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Arak University of Medical Sciences

Street address
Basij Square

City
Arak

Postal code

Approval date
2013-12-24, 1392/10/03

Ethics committee reference number
92-155-2

Health conditions studied

1

Description of health condition studied
nausea and vomiting after cesarean section by spinal anesthesia

ICD-10 code
O29.5

ICD-10 code description
Other complications of anaesthesia during pregnancy

Primary outcomes

1

Description
nausea and vomiting

Timepoint
1,2,4,6 hour after intervention

Method of measurement
quadruplicate score

Secondary outcomes

1

Description
drug side effect

Timepoint
1,2,4,6 after intervention

Method of measurement
quadruplicate score

Intervention groups

1

Description
First group (52 person)capsule gabapentin 300mg.

Category
Treatment - Drugs

2

Description
Second group (52 person) receive capsule ondansetron 8 mg.

Category
Treatment - Drugs

3

Description
Third group (52 person) receive capsule ginger 1 g.

Category
Treatment - Drugs

4

Description
Fourth group (52 person) receive capsule placebo.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Arak University of Medical Sciences

Full name of responsible person
Dr.Mehri Jamilian

Street address
Taleghani Hospital

City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr.Ashtiyani
Street address
Basij Square
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
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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