

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparing the effect of intraoperative cesarean wound lavage with gentamicin solution in wound infection with normal saline- A double blind randomized controlled clinical trial

Protocol summary

Summary

From August 2014 to August 2015, a randomized double-blinding clinical trial is conducted at two educational hospitals of Ahvaz Jundishapur University of Medical Sciences (Imam Khomeini hospital and Razi Hospital). A total of 360 eligible participants will be enrolled in the study. Inclusion criteria were cesarean section surgery less than 40 minutes and Pfannenstiel incision. Patients were excluded if they have with extreme obesity (>100 kg), Immunodeficiency, blood hypertension and diabetes mellitus. Participants will be randomly allocated into two study groups including control group and intervention group. The wounds of alternate patients were irrigated during surgery either with normal saline (300 cc) or with gentamicin solution (80 mg) plus normal saline (300 cc). Both groups will be followed during 30 days after surgery. Then they will be assessed for signs and symptoms of surgical-site infection as the primary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021221048N1**

Registration date: **2015-04-11, 1394/01/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-04-11, 1394/01/22

Registrant information

Name

Soghra Ariazanganeh

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3221 6504

Email address

ariazanganeh.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2014-08-22, 1393/05/31

Expected recruitment end date

2015-08-22, 1394/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of intraoperative cesarean wound lavage with gentamicin solution in wound infection with normal saline- A double blind randomized controlled clinical trial

Public title

Effect of Gentamicin and normal saline on post-cesarean infection

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: Cesarean section surgery less than 40 minutes, Pfannenstiel incision exclusion criteria: Obesity (>100 kg), Immunodeficiency diseases, hypertension and diabetes mellitus

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 360

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

in this study 0.9% Sodium Chloride Injection, Iran Pharmaceutical and Parenteral Co. and Gentamicin from Sobhan Rasht Co. will be used.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan blvd, central building Of AJUMS

City

Ahvaz

Postal code

Approval date

2015-02-02, 1393/11/13

Ethics committee reference number

AJUMS.REC.1393.315

Health conditions studied

1

Description of health condition studied

Post cesarian section subcutaneous infection

ICD-10 code

O86.0

ICD-10 code description

Infected: caesarean section wound perineal repair following delivery

Primary outcomes

1

Description

infection

Timepoint

30 days after cesarian section

Method of measurement

Redness, tenderness in the wound or wound dehiscence

2

Description

readmission

Timepoint

30 days after cesarian section

Method of measurement

more than 1 day readmission due to post cesarian section infection

Secondary outcomes

empty

Intervention groups

1

Description

Control group: The wounds of patients were irrigated with the 300 cc normal saline before closing the wound.

Category

Prevention

2

Description

Intervention group: The wounds of patients were irrigated with 300cc normal saline plus 80 mg gentamicin before closing the wound.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Street address

City

Ahvaz

2

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Street address

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Razieh Mohammad Jafari

Street address

Fertility Infertility and Perinatology Research Center.
Ahvaz Jundishapur University of Medical Sciences.

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jundishapur 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

Fertility Infertility and Perinatology Research Center,
Ahvaz Jundishapur University of Medical Scie

Full name of responsible person

Soghra Ariazanganeh

Position

Resident of Obstetrics and Gynecology

Other areas of specialty/work

Street address

Imam Khomeini Hospital, Azadegan street, Ahvaz,
Iran

City

Ahvaz

Postal code

Phone

+98 61 3221 6504

Fax

Email

ariazanganeh.s@ajums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Fertility Infertility and Perinatology Research Center,
Ahvaz Jundishapur University of Medical Scie

Full name of responsible person

Soghra Ariazanganeh

Position

Resident of Obstetrics and Gynecology

Other areas of specialty/work

Street address

Imam Khomeini Hospital, Azadegan street, Ahvaz,
Iran

City

Ahvaz

Postal code

Phone

+98 61 3221 6504

Fax

Email

ariazanganeh.s@Ajums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Neda Hamidipour

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

00

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