

# 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,  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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## 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**

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**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*