

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### The effect of using Gentamicin in subcutaneous tissue, before skin suturing at cesarean section infection

#### Protocol summary

##### Study aim

The effect of using gentamicin in subcutaneous tissue, before skin suturing at cesarean section infection

##### Design

A randomized clinical trial, with parallel groups, phase 3, double blind that 120 patients randomly divided into two groups of 60 subjects with block sizes of 4 and 6.

##### Settings and conduct

Patients referred to Imam Sari hospitals for cesarean section, randomly divided into two groups with block sizes of 4 and 6. Then they were assessed for signs and symptoms of surgical-site infection as the primary outcome.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 40 years, gestational age of early term (37 to 38 weeks and 6 days) and full term (39 to 40 weeks and 6 days), elective admission, having a live fetus and mental health of the mother, Pfannenstiel incision. Exclusion Criteria: Patients with known infections before surgery, underlying disorders such as diabetes and blood pressure, immune system deficiency diseases, history of taking drugs that weaken or strengthen the immune system, various cancers, coagulation disorders, malnutrition, and smoking and drug use and people with surgical wound infection in previous cesarean section.

##### Intervention groups

Intervention group: The wounds of patients were irrigated with 100cc normal saline plus 80 mg gentamicin before closing the wound. Control group: The wounds of patients were irrigated with the 100 cc normal saline before closing the wound.

##### Main outcome variables

infection

#### General information

##### Reason for update

Due to the spread of covid-19 and the reduction of

elective surgeries, therefore; The researcher decided to announce the change in the sample size and update the recorded information in this scientific database.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200126046261N1**

Registration date: **2020-05-14, 1399/02/25**

Registration timing: **prospective**

Last update: **2023-07-13, 1402/04/22**

Update count: **2**

##### Registration date

2020-05-14, 1399/02/25

##### Registrant information

##### Name

معصومه Masoomeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3325 7230

##### Email address

zakeri.m@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-08-22, 1399/06/01

##### Expected recruitment end date

2021-08-23, 1400/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of using Gentamicin in subcutaneous tissue, before skin suturing at cesarean section infection

**Public title**

The effect of Gentamicin at cesarean section infection

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Gestational age of early and full term Elective admission Having a live fetus Mother's mental health Pfannenstiel incision

**Exclusion criteria:**

Patients with known infection before surgery Having underlying diseases (diabetes, blood pressure, types of cancers) Patients with immune system deficiency Coagulation disorders Malnutrition Smoking and drug use People with a history of surgical wound infection in a previous cesarean section

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients were randomly divided into two groups of 60 subjects with four and six blocks and an allocation ratio of 1:1. Participants allocation sequence in two groups performed with a Randomizer software. Opaque sealed sequentially numbered envelopes used for allocation concealment

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participating patients and the surgeon did not know about receiving subcutaneous gentamicin.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran University Of

Medical Sciences

**Street address**

Vice -Chancellor for Research of Mazandaran University of Medical Sciences, Moalem Square

**City**

Sari

**Province**

Mazandaran

**Postal code**

4816715793

**Approval date**

2020-04-29, 1399/02/10

**Ethics committee reference number**

IR.MAZUMS.REC.1399.148

**Health conditions studied****1****Description of health condition studied**

Wound infection

**ICD-10 code**

O86.0

**ICD-10 code description**

Infection of obstetric surgical wound

**Primary outcomes****1****Description**

wound infection

**Timepoint**

The first day after surgery and the tenth and thirtieth day

**Method of measurement**

physical examination

**2****Description**

wound dehiscence

**Timepoint**

The first day after surgery and the tenth and thirtieth day

**Method of measurement**

physical examination

**Secondary outcomes****1****Description**

Pain in the operation area

**Timepoint**

The first day after surgery, the tenth day and the thirtieth day

**Method of measurement**

Visual Analogue Scale

## Intervention groups

### 1

#### Description

Intervention group: The wounds of patients were irrigated with 100 cc normal saline plus 80 mg gentamicin (Exir Pharmaceutical Company) before closing the wound

#### Category

Prevention

### 2

#### Description

Control group: The wounds of patients were irrigated with the 100 cc normal saline before closing the wound.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Khomeini Hospital

##### Full name of responsible person

Ebrahim Nasirifar

##### Street address

Sari, Imam Sq, Amir Mazandarani street

##### City

Sari

##### Province

Mazandaran

##### Postal code

4816633131

##### Phone

+98 11 3304 4000

##### Email

enasiri@mazums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Aliakbar Hedaiatzadeh

##### Street address

Vice Chancellor for Research of Mazandaran University of Medical Sciences, Moalem Square, Moalem Street. sari Mazandaran

##### City

Sari

##### Province

Mazandaran

##### Postal code

4817918479

##### Phone

+98 11 3325 7230

##### Email

akbar\_hedayati@mazums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

##### Full name of responsible person

Ebrahim nasirifar

##### Position

Assistant

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Traditional Medicine

##### Street address

Traditonal and complementary research center of Mazandaran University of Medical Sciences

##### City

Sari

##### Province

Mazandaran

##### Postal code

4847116548

##### Phone

+98 11 3354 3239

##### Email

enasiri@mazums.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Ebrahim Nasirifar

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Assistant

##### Latest degree

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**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Ebrahim nasirifar

**Position**

Assistant

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Street address**

Traditional and complementary research center of

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is still no plan for its publish.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available