

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### A comparative study of the reduction of wound infection in emergency cesarean section using and not using subcutaneous gentamicin

#### Protocol summary

##### Study aim

The effectiveness of subcutaneous gentamicin after emergency cesarean section

##### Design

Phase 3 randomized controlled clinical trial on 200 patients

##### Settings and conduct

Subcutaneous gentamicin injection after emergency cesarean section with a dose of 80 to 160 mg with a sterile syringe after the completion of the operation in the operating room, which is done after obtaining the consent of the patient, which will be done randomly in Khairin Salamat Qom hospital with the aim of wound infection prophylaxis. Blinding is not done

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: emergency cesarean section

Exclusion criteria: chorioamnionitis, use of antibiotic therapy

##### Intervention groups

Subcutaneous gentamicin injection in emergency cesarean section in the intervention group and no subcutaneous gentamicin injection in the control group and investigating the effect of subcutaneous gentamicin in reducing wound infection.

##### Main outcome variables

Investigating the effect of subcutaneous gentamicin on cesarean section infection

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221126056607N1**

Registration date: **2022-12-20, 1401/09/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-12-20, 1401/09/29**

Update count: **0**

##### Registration date

2022-12-20, 1401/09/29

##### Registrant information

###### Name

Fatemeh Mohammadkarimi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4407 1732

###### Email address

drfatemehkarimi68@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-11-28, 1401/09/07

##### Expected recruitment end date

2023-03-20, 1401/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparative study of the reduction of wound infection in emergency cesarean section using and not using subcutaneous gentamicin

##### Public title

اثر جنتامایسین زیرجلدی در کاهش عفونت زخم سزارین

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

emergency cesarean section

**Exclusion criteria:**

chorioamnionitis therapeutic antibiotic elective cesarean section

**Age**

No age limit

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: 200

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Also, allocation of patients to groups A and B will be done based on randomness (table of random numbers). The study is a blind one. The samples are randomly divided into two groups using blocks of 4 that are generated using a table of random numbers, and the groups are labeled with A, B codes and concealment with study drugs similar in color, consistency, Volume and packaging will be done. Therefore, patients will be assigned to two study groups using the random block allocation method

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

All patients are aware of participating in the study, but they do not know the type of treatment allocated (patients not knowing about treatment type A or B)

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics Committee of Qom University of Medical Sciences

**Street address**

azar street 15 khordad blv

**City**

Qum

**Province**

Ghous

**Postal code**

3715873355

**Approval date**

2022-11-23, 1401/09/02

**Ethics committee reference number**

IR.MUQ.REC.1401.163

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

wound infection after cesarean

**ICD-10 code**

086

**ICD-10 code description**

Infection of obstetric surgical wound

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

Caesarean section infection

**Timepoint**

42 days after the operation

**Method of measurement**

Observation of erythema and purulent discharge or positive culture from the caesarean section

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: In caesarean section patients, gentamicin ampoule is injected under the skin after closing the fascia with a dose of 80 mg, and then the skin is repaired (Aburihan Pharmaceutical Company)

**Category**

Prevention

**2****Description**

Control group: No subcutaneous gentamicin injection in emergency cesarean section.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Khayerin salamat hospital

**Full name of responsible person**

Fatemeh mohammadkarimi

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Ghoum University of Medical Sciences  
**Full name of responsible person**  
dr Rahim aali  
**Street address**  
saheli street Qom University of Medical Sciences  
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**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Ghoum 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**  
Ghoum University of Medical Sciences  
**Full name of responsible person**  
maryam yousefi  
**Position**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**

Gynecology and Obstetrics  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

#### Contact

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Patient data including age and gestational age and factors associated with infection can be shared

**When the data will become available and for how long**

A year after the publication of the article from 2022

**To whom data/document is available**

All people

**Under which criteria data/document could be used**

The collected data will only be studied in line with the objectives of the study and we will not have additional analysis

**From where data/document is obtainable**

drfatemehkarimi68@yahoo.com

**What processes are involved for a request to access data/document**

send mail

**Comments**