Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study of the reduction of wound infection in emergency cesarean section using and notusing subcutaneous gentamicin

Protocol summary

Study aim
The effectiveness of subcutaneous gentamicin after emergency caesarean section
Design
Phase 3 randomized controlled clinical trial on 200 patients
Settings and conduct
Subcutaneous gentamicin injection after emergency caesarean 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 caesarean section
Exclusion criteria: chorioamnionitis, use of antibiotic therapy
Intervention groups
Subcutaneous gentamicin injection in emergency caesarean 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 caesarean 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 notusing 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
Ghoum

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

Street address
Azar street 15khordad blv

City

Qum
Province
Ghoum
Postal code
3715873355
Phone
+98 21 4407 1732
Email
drfatemehkarimi68@yahoo.com

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
City
Qum
Province
Ghoum
Postal code
3715873355
Phone
+98 25 3133 1451
Email
drfatemehkarimi@yahoo.com
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
Street address
Azar street 15 khordad blv
City
Qum
Province
Ghoum
Postal code
3715873355
Phone
+98 25 3133 1451
Email
drfatemehkarimi68@yahoo.com

Person responsible for scientific 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
Street address
Azar street 15 khordad blv
City
Qum
Province
Ghoum
Postal code
3715873355
Phone
+98 25 3133 1451
Email
drfatemehkarimi68@yahoo.com

Person responsible for updating data

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
Street address
Azar street 15 khordad blv
City
Qum
Province
Ghoum
Postal code
3715873355

Phone
+98 25 3133 1451
Email
drfatemehkarimi68@yahoo.com

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