

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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

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4816633131

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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

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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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Assistant

Latest degree

Ph.D.

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant

Latest degree

Ph.D.

Other areas of specialty/work

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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