

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of nano antimicrobial dressings on the healing of wound infections following cesarean section and hysterectomy: A randomized Clinical Trial

Protocol summary

Study aim

The effect of nano antimicrobial dressings on the healing of wound infections following cesarean section and hysterectomy

Design

This study is a randomized clinical trial in a parallel design with a control group. In this single-blind study, patients are aware of participating in the study but are kept blind to the type of dressing. This study is randomized, phase 2-3 of the study will be performed on 100 subjects who have had a cesarean section. A random number table is used for randomization and participants are assigned to two groups of intervention and control.

Settings and conduct

This study, which will be performed in Imam Reza Hospital in Kermanshah, is single-blinded. Dressings are made in similar packages (produced by Danesh Bonyan Nano Textile Company of Aria Teb, white, odorless, and have a completely similar appearance to disposable dressings of Supa Company) for the purpose of blinding and the patient will not be aware of the type of dressing.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with evidence of localized cellulitis or wound redness or discharge from the incision cesarean section or hysterectomy; Informed consent
Exclusion criteria: Patients with a history of skin allergies to nanoproducts; Patients with systemic symptoms suggestive of impending doom fever, chills, or leukocytosis (more than 16 thousand) and need to be injected with antibiotics.

Intervention groups

The intervention group will be subjected to daily antimicrobial dressing until the wound is completely closed. The control group will be treated with sterile gauze daily.

Main outcome variables

Fever and chills, infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210705051790N1**

Registration date: **2021-09-14, 1400/06/23**

Registration timing: **prospective**

Last update: **2021-09-14, 1400/06/23**

Update count: **0**

Registration date

2021-09-14, 1400/06/23

Registrant information

Name

nasrin jalilian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3710 6522

Email address

njalilian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nano antimicrobial dressings on the healing of wound infections following cesarean section and hysterectomy: A randomized Clinical Trial

Public title

The effect of nano antimicrobial dressings on the healing of wound infections

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with evidence of localized cellulitis or wound redness or discharge from the incision cesarean section or hysterectomy Informed consent

Exclusion criteria:

Patients with a history of skin allergies to nanoproducts
Patients with systemic symptoms suggestive of impending doom fever, chills or leukocytosis (more than 16 thousand) and need to be injected with antibiotics.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the random number table, patients are divided into two groups. Each patient is assigned a 4-digit code based on the random number table, based on the right number of patients' codes, the patients are divided into two groups. Patients whose last digit is 2, 4, 6, 8 will be assigned to the intervention group and patients whose last digit is 1,3,5, 7 will be assigned to the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, patients in either group will not know whether the dressing is antimicrobial or a sterile gauze dressing. In such a way that the dressings will be used in similar packages (produced by Danesh Bonyan Nano Nesaj Aria Teb, white, odorless, and completely similar to the disposable dressings of Supa Company) and the patient will not be aware of the type of dressing.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2021-04-27, 1400/02/07

Ethics committee reference number

IR.KUMS.REC.1400.155

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

Infection following cesarean section

ICD-10 code

T81.4

ICD-10 code description

Infection following a procedure

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

Ague

Timepoint

At the time of hospitalization (average 2 to 3 days after surgery), 4 to 7 days after surgery, 2 weeks after discharge.

Method of measurement

Question from the patient

2**Description**

Infection

Timepoint

At the time of hospitalization (average 2 to 3 days after surgery), 4 to 7 days after surgery, 2 weeks after discharge.

Method of measurement

Examination and observation by a physician

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will be subjected to once a day antimicrobial dressing until the wound is completely closed

Category

Treatment - Other

2

Description

The control group will be treated with sterile gauze once a day

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr. Nasrin Jalilian

Street address

Emam Reza Hospital, Parastar Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr.Reza Khodarahmi

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Nasrin Jalilian

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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