Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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
City
kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3427 6306
Email
njalilian@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr.Reza Khodarahmi
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
Phone
+98 83 3836 0014
Email
rkhodarahmi@kums.ac.ir
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
Street address
Emam Reza Hospital, Parastar Boulevard
City
kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3427 6306
Email
njalilian@yahoo.com

Person responsible for scientific 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

Street address

Emam Reza Hospital, Parastar Boulevard

City

kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

njalilian@yahoo.com

Person responsible for updating data

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

Street address

Emam Reza Hospital, Parastar Boulevard

City

kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

njalilian@yahoo.com

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