Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluating the Efficacy of an Innovative Chitosan Dressing Compared to Routine Hospital Dressing on Wound Healing, Postoperative Pain, and Surgical Site Infection Following Cesarean Section: A Randomized Controlled Clinical Trial

Protocol summary

Study aim
To determine and compare the efficacy of an innovative chitosan nanofiber dressing versus routine hospital dressing on wound healing, postoperative pain, and surgical site infection (SSI) following elective primary cesarean section.

Design
A randomized, parallel-group, single-blind, controlled clinical trial, phase 2-3, on 68 elective cesarean mothers.

Settings and conduct
This single-blind clinical trial will be conducted at a university hospital of Mashhad University of Medical Sciences. Eligible elective cesarean mothers are randomized (1:1) into intervention (chitosan dressing) or control groups using variable block randomization. Patients are blinded to the dressing applied under anesthesia in the operating room.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Written informed consent, maternal age 18 to 40 years, gestational age 37 to 41 full weeks, elective primary cesarean section with transverse incision, body mass index (BMI) under 35, and absence of systemic diseases affecting wound healing or immunosuppressive medications. Exclusion Criteria: severe intraoperative bleeding requiring blood transfusion, surgery duration exceeding 90 minutes, non-cooperation with follow-up, and need for wound re-exploration or secondary abdominal surgery during the recovery period.

Intervention groups
In the intervention group, immediately following cesarean skin closure in the operating room, the surgical incision is covered with an innovative biocompatible chitosan nanofiber dressing.

Main outcome variables
pain, wound healing, and surgical site infection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220712055438N5**
Registration date: **2026-11-04, 1405/08/13**
Registration timing: **prospective**

Last update: **2026-11-04, 1405/08/13**
Update count: **0**

Registration date
2026-11-04, 1405/08/13

Registrant information

Name
Sedigheh Abdollahpour
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3841 7660
Email address
abdollahpourts2@yahoo.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-11-21, 1405/08/30

Expected recruitment end date
2027-05-20, 1406/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluating the Efficacy of an Innovative Chitosan Dressing Compared to Routine Hospital Dressing on Wound Healing, Postoperative Pain, and Surgical Site Infection Following Cesarean Section: A Randomized Controlled Clinical Trial

Public title
Comparison of Chitosan Dressing and Routine Dressing on Cesarean Wound Healing, Pain, and Infection

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Provision of written informed consent to participate in the study.Maternal age between 18 and 40 years.Gestational age between 37 completed weeks and 41 weeks (based on first-trimester ultrasound or confirmed LMP).Primiparous women undergoing elective Cesarean section with a transverse lower uterine segment incision (Pfannenstiel incision).Body Mass Index (BMI) less than 35 kg/m² at the time of hospital admission.Absence of underlying systemic medical conditions known to impair wound healing (e.g., pre-gestational or gestational diabetes, autoimmune disorders, chronic kidney or liver disease, and coagulopathies).No history of receiving immunosuppressive agents, systemic corticosteroids, or chemotherapy within the preceding three months.

Exclusion criteria:

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible participants will be allocated to either the intervention or control group with a 1:1 allocation ratio using permuted block randomization with variable block sizes of 4 and 6. The random allocation sequence will be generated by an independent statistical consultant (not involved in clinical intervention or outcome assessment) using computer-generated random sequences to maintain group balance and prevent allocation sequence predictability.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is designed as a single-blind randomized controlled trial. Because the dressing is applied onto the surgical incision in the operating room immediately following Cesarean section while the mother is under regional or general anesthesia, the participant remains completely blinded to the allocated intervention (chitosan dressing versus routine hospital dressing). Due to physical and visual distinctions between the two dressing types, blinding of the healthcare provider and the outcome assessor is not feasible.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Vakilabad

City
mashhad

Province
Razavi Khorasan

Postal code
9183887654

Approval date
2026-11-03, 1405/08/12

Ethics committee reference number
IR.MUMS.NURSE.REC.1405.094

Health conditions studied

1

Description of health condition studied
Surgical wound healing, postoperative pain, and surgical site infection (SSI) following cesarean section

ICD-10 code
O86.0 O90.

ICD-10 code description
عوارض جراحی مامایی و زایمان (شامل عفونت زخم جراحی مامایی و اختلال ترمیم زخم سزارین)

Primary outcomes

1

Description
Wound Healing

Timepoint
on days 2, 7, 14, and 30 post-surgery

Method of measurement
Assessed using the REEDA scale

2

Description
Postoperative Pain
Timepoint
on days 2, 7, 14, and 30 post-surgery.
Method of measurement
Visual Analog Scale (VAS)

3

Description
Surgical Site Infection (SSI)
Timepoint
on days 2, 7, 14, and 30 post-surgery.
Method of measurement
Clinical evaluation of infection signs based on CDC criteria

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: mmediately following skin closure in the operating room, the surgical incision is covered with an innovative chitosan nanofiber dressing.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospitals affiliated with Mashhad University of Medical Sciences (Obstetrics and Gynecology wards an
Full name of responsible person
Sedigheh Abdollahpour
Street address
Vakilabad Blvd, Shahid Bahonar Blvd, University Campus, Kharazmi Building, School of Nursing and Midwifery
City
Mashhad
Province
Razavi Khorasan
Postal code
9177943760
Phone
+98 915 133 0217
Email
abdollahpoursd@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Vakilabad Blvd, Shahid Bahonar Blvd, University Campus, Kharazmi Building, School of Nursing and Midwifery
City
Mashhad
Province
Razavi Khorasan
Postal code
9177943760
Phone
+98 915 133 0217
Email
abdollahpourts2@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Sedigheh Abdollahpour
Position
PhD on reproductive health
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Vakilabad Blvd, Shahid Bahonar Blvd, University Campus, Kharazmi Building, School of Nursing and Midwifery
City
Mashhad
Province
Razavi Khorasan
Postal code
9177943760

Phone
+98 51 3841 7660
Fax
Email
abdollahpourts2@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Sedigheh Abdollahpour
Position
PhD on reproductive health
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Vakilabad Blvd, Shahid Bahonar Blvd, University Campus, Kharazmi Building, School of Nursing and Midwifery
City
Mashhad
Province
Razavi Khorasan
Postal code
9177943760
Phone
+98 51 3841 7660
Fax
Email
abdollahpourts2@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Sedigheh Abdollahpour
Position
PhD on reproductive health
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Vakilabad Blvd, Shahid Bahonar Blvd, University Campus, Kharazmi Building, School of Nursing and Midwifery
City
Mashhad
Province
Razavi Khorasan
Postal code
9177943760
Phone
+98 51 3841 7660
Fax
Email
abdollahpourts2@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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
De-identified individual participant data (IPD), the study protocol, and the statistical analysis plan will be available 6 months following the publication of the final trial results. Data will be shared upon reasonable academic request for scientific research or meta-analyses, subject to ethics committee approval and agreement of the corresponding author via official correspondence.
When the data will become available and for how long
Beginning 6 months and ending 3 years following article publication.
To whom data/document is available
Academic researchers and investigators in reproductive health and wound care fields for research purposes and meta-analyses (upon approval of the corresponding author).
Under which criteria data/document could be used
Exclusively for scientific research, systematic reviews, and meta-analyses, provided that data confidentiality is maintained, commercial use is avoided, and proper citation of the main article is ensured.
From where data/document is obtainable
Corresponding author (Research Deputy / Department of Midwifery, Mashhad University of Medical Sciences), via official email request.
What processes are involved for a request to access data/document
Submission of a formal written request and brief proposal to the corresponding author, evaluation of the request by the research team and ethics committee within a specified timeframe (max one month), and upon approval, secure transfer of de-identified data via email.
Comments