Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study of the effect of chitosan wound dressing containing antibiotics on recovering process of the infected wounds

Protocol summary

Study aim
Investigating the effectiveness of chitosan wound dressings containing antibiotics on surgical wounds, bedsores, transplant wounds, burn wounds, diabetic foot wounds, infectious wounds, and wounds prone to infection.

Design
A controlled, single-blind, randomized, phase 3 clinical trial on 20 patients.

Settings and conduct
The wound dressing will be prepared at Medical Biomaterials Research Center Tehran University of Medical Sciences. Patients referred to Farmaniyeh Hospital are selected by a specialist doctor. The dressing will be placed on the damaged wound and its healing process will be monitored by the attending physician for a week and every day after dressing.

Participants/Inclusion and exclusion criteria
Patients with surgical wounds, bedsores, transplant site wounds, diabetic foot and infected wounds and wounds prone to infection will be included in the study. Patients with deep wounds with abscess, osteomyelitis, presence of local or extensive non-debriding gangrene, venous ulcers, malignancy in the wound area, and pregnant women will be excluded from the study.

Intervention groups
The intervention group is the group that will receive the chitosan wound dressing containing antibiotics, and the control group is the group that will receive the usual dressing as a wound dressing.

Main outcome variables
Wound quality and healing of infection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211127053186N2**
Registration date: **2024-01-23, 1402/11/03**
Registration timing: **prospective**

Last update: **2024-01-23, 1402/11/03**
Update count: **0**

Registration date
2024-01-23, 1402/11/03

Registrant information
Name
Somayeh Handali
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-14, 1402/11/25

Expected recruitment end date
2026-03-20, 1404/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the effect of chitosan wound dressing containing antibiotics on recovering process of the infected wounds

Public title
The effect of chitosan wound dressing in the treatment of infected wounds

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
"Patients with surgical wounds" are eligible for the study. "Patients with ulcers caused by bedsores" are eligible for the study. "Patients with diabetic foot ulcers" are eligible for the study. "Patients with wounds caused by infectious " are eligible for the study.
Exclusion criteria:
"Patients who have a deep wound with abscess, osteomyelitis, the presence of local or extensive non-debrideable gangrene" are not eligible for the study. "Patients with venous ulcers and evidence of malignancy in the wound area" are not eligible for the study. "Pregnant women diagnosed by a specialist doctor" are not eligible to enter the study.
Age
From **40 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done in a simple way and the table of random numbers will be used as a tool. Even numbers are for the intervention group and odd numbers are for the control group. Then, according to the number of the studied sample, the corresponding numbers are extracted from the table of random numbers or using a computer, and each number is written on a card and placed in an envelope, and the envelopes are sealed, and on each envelope the number The patient is written. The first patient who is enrolled in the study and enters the study will be given the envelope related to patient number 1, patient number 2 will be given envelope number 2 and so on, and this will continue until the end of the study sample. In order to maintain randomization, the person who prepares the envelopes will be different from the person who registers the patients and provides the envelopes to the patients.
Blinding (investigator's opinion)
Single blinded
Blinding description
Only study participants are blinded. This means that only the participants do not know which group they have been placed in and whether they have been prescribed a drug or a placebo. It is tried that the patients do not meet each other during their visits, and their appointments are made separately at different times. During wound dressing, all patients will be told that the same dressings will be used for them.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Englebal, 16 Azar St., Tehran University of Medical Sciences1417653761
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2023-12-14, 1402/09/23
Ethics committee reference number
IR.TUMS.TIPS.REC.1402.122

Health conditions studied

1

Description of health condition studied
Infected wounds
ICD-10 code
S01.0
ICD-10 code description
Open wound of scalp

Primary outcomes

1

Description
Wound healing percentage
Timepoint
The wound healing process is monitored every day for a week.
Method of measurement
Taking a photo of the wound and comparing the photo of the first day with the photo of the seventh day

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The wound dressing is prepared in the laboratory of Medical Biomaterials Research Center (MBRC) in Tehran University of Medical Sciences. Patients referred to Farmanieh Hospital are selected by a specialist doctor. A chitosan dressing containing antibiotics will be placed on the affected wound. The wound dressing is changed and controlled by the attending physician every day for a week.

Category
Treatment - Drugs

2

Description
Control group: Wound dressing is prepared in the laboratory of Medical Biomaterial Research Center (MBRC) in Tehran University of Medical Sciences. Patients referred to Farmanieh Hospital are selected by a specialist doctor. A chitosan dressing will be placed on the affected wound. The wound dressing is changed and controlled by the attending physician every day for a week.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Farmaniyeh Hospital

Full name of responsible person
Somayeh Handali

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Englebal, 16 Azez, Tehran University of Medical Sciences

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Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

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Grant name
Vice President of Research, Tehran University of Medical Sciences- Medicine Biomaterials Research Center (MBRC)

Grant code / Reference number
1402-3-229-67500

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Somayeh Handali

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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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
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The data from this study will be published as an article or a report.

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
The resulting data will be available for researchers working in academic and scientific and clinical institutions

Under which criteria data/document could be used
There are no special conditions.

From where data/document is obtainable
To receive the data, applicants can refer to Tehran University of Medical Sciences, located on 16 Azar St.

What processes are involved for a request to access data/document
Researchers can access the data by searching the Internet.

Comments