

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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)

Phone

+98 21 6412 1510

Email address

s-handali@sina.tums.ac.ir

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 Sciences 1417653761

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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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Person responsible for scientific inquiries

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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