

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Clinical trial of the Efficacy of Chitosan Hydrogel Wound dressing Loaded with two Antibiotics with Synergistic Effects for Healing of Wounds in Burn Patients

Protocol summary

Study aim

The evaluation of the safety and efficiency of the chitosan hydrogel system and the investigation of the synergistic effect of the optimized concentrations of antibiotics in preventing the progress of infection and healing the tissue of burn wounds is in phase one of the Clinical Trial.

Design

Clinical trial with control group, with parallel groups, double blind, non-random, phase 1 on 50 patients.

Settings and conduct

Infectious second degree burn patients are selected from those who refer to Zare Hospital. In this way, all the patients who enter, provided they meet the entry criteria and do not have the exit criteria and complete the consent form until the required number of the study is filled, are accepted and entered the study without exception.

Participants/Inclusion and exclusion criteria

Patients with 2nd degree burns whose wounds have secretory exudate. The size of the wound is greater than or equal to 10 cm. The location and shape of the wound can be divided into two separate areas. No more than a week has passed since the patients were hospitalized.

Intervention groups

Group A: Wound covered with antibacterial chitosan hydrogel dressing. Group B: wound covered with sulfadiazine antibacterial dressing. In each of the patients, the wounds are treated simultaneously in 2 methods A and B (Within-person RCT), in such a way that depending on the extent of the wound, the wound is divided into two equal parts, left and right or upper and lower.

Main outcome variables

Wounds are evaluated during the 21-day treatment period. On day zero, biopsy and exudate are taken from the wound and bacterial culture is performed. Then every 6 days, exudate samples are taken from the

wound and bacterial culture is done to record the bacteria count by colony counting method. Wounds are photographed every 3 days and redness, inflammation and pain are recorded according to the checklist.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230715058787N1**

Registration date: **2023-10-23, 1402/08/01**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-23, 1402/08/01**

Update count: **0**

Registration date

2023-10-23, 1402/08/01

Registrant information

Name

Samaneh Kiani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4426 2584

Email address

samanekiani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial of the Efficacy of Chitosan Hydrogel Wound dressing Loaded with two Antibiotics with Synergistic Effects for Healing of Wounds in Burn Patients

Public title
Burn repair with Chitosan dressing

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with 2nd degree burns whose wounds have secretory. exudate The size of the wound is greater than or equal to 10 cm. The location and shape of the wound should be such that it can be divided into two separate areas. No more than a week has passed since the patients were hospitalized.

Exclusion criteria:
Burn wounds without secretory exudate Electrical, chemical and frostbite burns Patients who have used commercial treatments other than the conventional method. Patients with systemic blood problems, kidney, liver and heart problems, and diabetic patients

Age
No age limit

Gender
Both

Phase
1

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: 50

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient is unaware of the type of dressing used in each part of the wound, that is, he does not know which dressing is the main group and which is the control group. On the other hand, the surgeon who performs the dressing, the experienced nurse who records the history, and the doctor who evaluates the treatment result are three separate people. In this way, photos and histories are prepared and coded according to the checklist of the intervention and wound control parts at the designated times by the nurse (who is independent from the dressing and evaluator) and the photos are taken by the evaluating doctor who is from The type of dressing used in each photo is unknown, it is checked and the results are recorded

Placebo

Used
Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Working Group in Biomedical Research
Mazandaran University of Medical Sciences
Street address
Mazandaran university of Medical Sciences ,Km 18
Farah Abad, Sari
City
Sari
Province
Mazandaran
Postal code
4815733971
Approval date
2022-01-10, 1400/10/20
Ethics committee reference number
IR.MAZUMS.REC.1400.669

Health conditions studied

1

Description of health condition studied
Burn
ICD-10 code
L99
ICD-10 code description
سایر اختلالات پوست و بافت زیر جلدی در بیماری هایی که در جای دیگر طبقه بندی شده اند

Primary outcomes

1

Description
Wound healing
Timepoint
At the beginning of the study (before the start of the intervention) and then every 3 days for 21 days
Method of measurement
Wounds are evaluated during the 21-day treatment period. On day zero, biopsy and exudate are taken from the wound and bacterial culture is performed. Then every 6 days, exudate samples are taken from the wound and bacterial culture is done to record the bacteria count by colony counting method. Wounds are photographed every 3 days and redness, inflammation and pain are recorded according to the checklist. The healing percentage is calculated with the following

formula: Healing percentage in the wound (%) = ((area before treatment - area after treatment)/area before treatment) * 100

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This study aims to investigate the effect of chitosan hydrogel containing two antibiotics and its local effect in removing burn damage and accelerating burn wound healing. In this study, the addition of antibiotics (colistin and meropenem at 8 and 4 µg/liter, respectively) to chitosan hydrogel dressing is evaluated. and then covered with sores. If the wound has a lot of exudate, the wound is changed every day. In cases of low exudate, the dressing is changed every three days. In addition, for the coordination and proper implementation of the project, 2 training sessions were held for 4 hours between the technical team and the manufacturer of chitosan wound dressing and the treatment staff of Zare Hospital.

Category

Treatment - Drugs

2

Description

Sulfadiazine antibacterial dressing

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zare Psychiatric and Burn Hospital

Full name of responsible person

Dr. Mohammad Hossein Hosami Rostami

Street address

3 km of Sari Neka road, Zare psychiatric and burn hospital

City

Sari

Province

Mazandaran

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4843185774

Phone

+98 11 3328 3889

Email

samanekiani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Amir Mellati

Street address

Mazandaran University of Medical Sciences, 18th km of Farah Abad Road

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Postal code

۴۸۱۵۷۳۳۹۷۱

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amirmellati@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Amir Mellati

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Tissue Engineering

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

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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

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

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

Analytic Code

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

Data Dictionary

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