

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of safety of hydrogel wound dressing based on polyacrylic acid and xanthan gums in patients with 2nd thickness burns (Clinical trial phase I)

Protocol summary

Study aim

Evaluation of safety of hydrogel wound dressing based on polyacrylic acid and xanthan gums in patients with 2nd thickness burns (Clinical trial phase I)

Design

A nonrandomized clinical trial (phase I), without a control group and without blinding, will be conducted on 6 volunteer patients.

Settings and conduct

The study will be performed in Velayat Hospital. 6 Men or women with second-degree Burning areas under 10% will be selected and enrolled in the study after signing a consent form. Wounds are first washed with normal saline, Then a hydrogel dressing based on polyacrylic acid and xanthan gum is placed on the wound and bandaged with sterile gauze. Before intervention and at the end of 1, 3 and, 7 days changes in burning parameters will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria are an adult patient between 18 and 65 years of age with thermal burns of less than 10% of the total body surface area. Exclusion criteria are the existence of underlying disease affecting the wound healing and the presence of electrical or chemical burns.

Intervention groups

Synthetic hydrogel based on polyacrylic acid and xanthan gum will be used as a wound dressing on the second burn degree around 10%, and then, we will investigate local and systemic outcomes in 1, 3, and 7 time intervals.

Main outcome variables

Local and systemic outcomes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161001030072N3**

Registration date: **2023-05-10, 1402/02/20**

Registration timing: **prospective**

Last update: **2023-05-10, 1402/02/20**

Update count: **0**

Registration date

2023-05-10, 1402/02/20

Registrant information

Name

Siamak Rimaz

Name of organization / entity

Guilan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 8540

Email address

smkrimaz@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-21, 1402/02/31

Expected recruitment end date

2024-05-20, 1403/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety of hydrogel wound dressing based

on polyacrylic acid and xanthan gums in patients with 2nd thickness burns (Clinical trial phase I)

Public title
Investigation of the effect of hydrogel wound dressing based on polyacrylic acid and xanthan gum in the treatment of burn injury

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Thermal burns with flame or boiling water Second degree burns Burn percent range less than 10% Refer to the treatment center within less than 24 hours after the burn Normal hemoglobin and total protein levels are normal Male or female patients in age range 18 to 65 years Written consent form by the patients Body mass index between 18-30 kg/m2
Exclusion criteria:
Having background diseases (anemia, diabetes, cardiovascular diseases, immunodeficiency disorder) Lactating women Pregnant women

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **6**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

3th floor, Burn and Regenerative Medicine Research Center, Velayat Hospital, Namjo street, Rasht, Guilan

City

Rasht

Province
Guilan
Postal code
4193713194
Approval date
2023-05-02, 1402/02/12
Ethics committee reference number
IR.GUMS.REC.1402.054

Health conditions studied

1

Description of health condition studied

Second degree burn

ICD-10 code

T20

ICD-10 code description

Burn and corrosion of head, face, and neck

Primary outcomes

1

Description

Local out comes

Timepoint

At the beginning of the study (before the intervention) and 1, 3 and 7 days after applying the hydrogel wound dressing

Method of measurement

Clinical observations and filling the checklist in 4 time points

Secondary outcomes

1

Description

Systemic outcomes

Timepoint

At the beginning of the study (before the intervention) and 1, 3 and 7 days after applying the hydrogel wound dressing

Method of measurement

Clinical observations and filling the checklist in 4 time points

Intervention groups

1

Description

In the intervention group: before studying the wound, patients are examined by a doctor based on a checklist. Wounds are first washed with normal saline, Then a hydrogel dressing based on polyacrylic acid and xanthan gum (Masiha Eltiam Gostaran company) is placed on the wound and bandaged with sterile gauze. Burning parameter changes will be measured before intervention and at the end of 1, 3 and, 7 days.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Velayat Hospital

Full name of responsible person

Dr. Siamak Rimaz

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Center, Velayat hospital, Namjo street, Rasht, Guilan**City**

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smkrimaz@gums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Dr.Mohammadreza Naghipour

Street addressDeputy of Research and Technology, Shahid Siadati
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rasht 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**

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Reza Mobayen

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Email

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