Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

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

Protocol summary

Study aim

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

Design

A randomized clinical trial (phase II), with a control group and without blinding, will be conducted on 42 volunteer patients.

Settings and conduct

The study will be performed in Velayat Hospital. 42 Men or women with second-degree Burning areas between 20-50% will be selected and enrolled in the study after signing a consent form. Wounds are first washed with normal saline, Then, according to groups type (intervention or control) a hydrogel dressing based on polyacrylic acid and xanthan gum or commercial hydrogel is placed on the wound and bandaged with sterile gauze. Before intervention and at the end of 1, 3 and, 7,14 and 28 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 between 20% -50% 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

In the intervention group, the wounds are first washed with normal saline. Then polyacrylic acid hydrogel dressing and xanthan gum (Masiha Eltiam Gostaran company) is placed on the burn wound and bandaged with sterile gauze. And in the control group, after washing with normal saline, the wounds are treated with routine hydrogel dressing in the market (Berntech). Then the burn parameters will be measured in 0, 1, 3, 7, 14 and 28 days after hydrogel application.

Main outcome variables

Local outcomes, Systemic outcomes, Hospital stay, Graft percent to TBSA percent ratio; Total fluid requirement; Infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161001030072N4**
Registration date: **2023-10-04, 1402/07/12**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-04, 1402/07/12**
Update count: **0**

Registration date

2023-10-04, 1402/07/12

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

2023-10-02, 1402/07/10

Expected recruitment end date

2024-05-30, 1403/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

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 Between 20-50% 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

3

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, in order to assign patients to the intervention and control groups, the restricted randomization approach will be used in parallel with the Random Allocation Rule method. In the random assignment process, the person who creates the random sequence is the analyst in this study. Also, the person who registers the participants based on the entry and exit criteria in the study will be one of the clinic nurses, and the person who allocates the participants in the intervention and control groups will be the project manager.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

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

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

City

Rasht

Province

Guilan

Postal code

4193713194

Approval date

2023-09-13, 1402/06/22

Ethics committee reference number

IR.GUMS.REC.1402.322

Health conditions studied

1

Description of health condition studied

Second degree burn

ICD-10 code

T20.0

ICD-10 code description

Burn of unspecified degree 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, 7, 14 and 28 days after applying the hydrogel wound dressing

Method of measurement

Clinical observations and filling the checklist in 6 time points

2

Description

Systemic outcomes

Timepoint

At the beginning of the study (before the intervention) and 1, 3, 7, 14 and 28 days after applying the hydrogel wound dressing

Method of measurement

Clinical observations and filling the checklist in 6 time points

Secondary outcomes

1

Description
Infection
Timepoint
At the beginning of the study (before the intervention) and 1, 3, 7,14, and 28 days after applying the hydrogel wound dressing
Method of measurement
Based on examination done by evaluators

2

Description
Hospital stay
Timepoint
At discharge
Method of measurement
Based on patients' files

3

Description
Total fluid requirement
Timepoint
At discharge
Method of measurement
Based on patients' files

4

Description
Graft to TBSA (total body surface area) percent ratio
Timepoint
At the admission
Method of measurement
Measurements based on Wallace criteria

Intervention groups

1

Description
Intervention group: Before strarting the study, patients wound 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, 7, 14 and 28 days.
Category
Treatment - Other

2

Description
Control group: Before studying, the patient's wounds are examined by a doctor based on a checklist. Wounds are first washed with normal saline, Then commercial hydrogel dressing (Burntec) is placed on the wound and bandaged with sterile gauze. Burning parameter changes will be measured before hydrogel applying and at the end of 1,3,7, 14, and 28 days.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat Hospital
Full name of responsible person
Dr. Siamak Rimaz
Street address
3rd floor, Burn and Regenerative Medicine Research Center, Velayat hospital, Namjo street, Rasht, Guilan
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 3336 8540
Fax
+98 13 3336 8540
Email
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 address
Deputy of Research and Technology, Shahid Siadati Street, Namjoo Street, Rasht, Guilan
City
Rasht
Province
Guilan
Postal code
4144666949
Phone
+98 13 3333 5820
Email
research@gums.ac.ir
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
Street address
3rd floor, Burn and Regenerative Medicine Research Center, Velayat Hospital, Namjo street, Rasht, Guilan
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 3336 8540
Email
Maziar.mobayen@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Mobayen
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
3th floor, Burn and Regenerative Medicine Research Center, Velayat Hospital, Namjo street, Rasht, Guilan
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 3336 8540
Email
Maziar.mobayen@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr. Mohammadreza Mobayen
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
3th floor, Burn and Regenerative Medicine Research Center, Velayat Hospital, Namjo street, Rasht, Guilan
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 3336 8540
Email
Maziar.mobayen@gmail.com

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