

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Safety and efficacy assessment of Polyurethane film for healing superficial second-degree (partial thickness) burns: Phase 1 clinical trial

Protocol summary

Study aim

Safety and efficacy assessment of Polyurethane (PU) film for healing superficial second-degree burns

Design

The study is phase 1 clinical trial. In this study, 10 patients with superficial Second-Degree burn between 10 to 25 percent total burn surface area was selected. The sampling is voluntary. The study is not blinded.

Settings and conduct

The site of the study is Imam Musa Kazim hospital of Isfahan. A part of superficial second degree burn area (excluding sensitive areas of the body) is covered with a piece of 8×8 cm² transparent PU film. The patient condition and burned area are checked every day.

Participants/Inclusion and exclusion criteria

Inclusion criteria: (1) Female or male between 18 and 60 years old; (2) Second-degree burns; (3) Total burn surface area between 10-25%. Exclusion criteria: (1) Presence of underlying medical conditions; (2) Subjects with Systemic infections receiving antibiotic treatment; (3) Need to consumption immunosuppressive drugs, Corticosteroids or chemotherapy; (4) Pregnancy, breastfeeding, and presence of trauma.

Intervention groups

First, the blisters and dead tissue of the wound are removed and the burned area is washed. Then a piece of 8×8 cm² transparent PU film is placed on a part of the superficial 2nd degree burn (except for the sensitive areas of the body) and fixed with sterile gas or bandage. The patient is hospitalized or referred to the hospital during treatment and the patient's condition and burned area are checked.

Main outcome variables

Healing time (day); Pain, itching and burning (0 to 10); The color of the wound from the beginning to the end of the treatment (Pink, red, brown or gray); Amount of exudate\inflammation (0 to 3).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210414050966N1**

Registration date: **2021-09-09, 1400/06/18**

Registration timing: **prospective**

Last update: **2021-09-09, 1400/06/18**

Update count: **0**

Registration date

2021-09-09, 1400/06/18

Registrant information

Name

Sayed Mohammad Razavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5579

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razavi@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy assessment of Polyurethane film for healing superficial second-degree (partial thickness) burns: Phase 1 clinical trial

Public title

Safety and efficacy assessment of Polyurethane film for healing superficial second-degree burns

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female or male between 18 and 60 years old Second-degree burn that are expected to heal in two to three weeks. Burns have been caused by contact with a heat source or hot liquids. Total body surface area in burns (TBSA) between 10% - 25% based on Lund and Browder chart Burned within the first 72 hours. No signs of infection in the wound

Exclusion criteria:

Presence of Underlying Medical Conditions such as dermatosis, allergy, cancer, renal failure, anemia, diabetes, cardiovascular disease, malignancy, immunodeficiency Injury to burn wounds during care Subjects with systemic infections receiving antibiotic treatment Need to consumption immunosuppressive drugs, Corticosteroids, chemotherapy, and radiation therapy during the experiment Subjects declined participation and no referral to the hospital for continuing the treatment Pregnancy, breastfeeding, and presence of trauma

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **10**

More than 1 sample in each individual

Number of samples in each individual: **1**

In each sample, a part of the superficial second degree burn is covered with the Polyurethane film .

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 Isfahan University of Medical Sciences

Street address

Hezar Jerib Street

City

Isfahan

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Postal code

8174673461

Approval date

2021-02-27, 1399/12/09

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.827

Health conditions studied

1

Description of health condition studied

Burn of superficial second-degree

ICD-10 code

T30.2

ICD-10 code description

Burn of second degree, body region unspecified

Primary outcomes

1

Description

Inflammation

Timepoint

Daily

Method of measurement

Based on the physician's observation

2

Description

Itching and burning

Timepoint

Daily

Method of measurement

According to the VAS criteria

Secondary outcomes

1

Description

Healing time

Timepoint

Daily

Method of measurement

Based on the physician's observation

2

Description

Amount of pain

Timepoint

Daily

Method of measurement

According to the VAS criteria

3

Description

color of burn wound

Timepoint

Daily

Method of measurement

Based on the physician's observation

4

Description

Amount of exudate

Timepoint

Daily

Method of measurement

Based on the physician's observation

Intervention groups

1

Description

For patients with second-degree burn, at first blisters and dead tissue are removed and the wound area is washed with a disinfectant solution (such as hexisept (chlorhexidine), actinisept, or 0.5% sodium hypochlorite (500 ppm)). Then a piece of PU film with dimensions of 8* 8 cm² is placed on a part of the superficial 2nd degree burn (except for the sensitive areas of the body) and fixed with sterile gas or bandage. The dressing remains on the burn area for the entire duration of the treatment with the approval of the doctor. During 14 to 21 days of treatment, the patient was hospitalized or referred to the hospital again and the general condition of the patient and the place covered with PU film are checked.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Musa Kazim hospital of Isfahan

Full name of responsible person

Fereydoon Abedini

Street address

Kaveh Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Avicenna Center of Excellence

Full name of responsible person

Shaghayegh Haghjooy Javanmard

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School of Advanced Technologies in Medicine, Isfahan
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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

Avicenna Center of Excellence

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

Esfahan University of Medical Sciences

Full name of responsible person

Sayed Mohammad Razavi

Position

Professor and faculty member of the Department of Oral and Maxillofacial Pathology, school of Dentis

Latest degree

Specialist

Other areas of specialty/work

Pathology

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

Esfahan University of Medical Sciences

Full name of responsible person

Fereydoon Abedini

Position

General Surgeon and member of Department of surgery and burn center team of Imam Musa Kazim Hospital

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data**Contact****Name of organization / entity**

Isfahan University of Technology

Full name of responsible person

Saied Nouri-Khorasani

Position

Professor of Polymer Group, Dept. of Chemical Engineering

Latest degree

Ph.D.

Other areas of specialty/work

Polymer Engineering

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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

Not applicable

Data Dictionary

Not applicable