

# 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 cm<sup>2</sup> 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 cm<sup>2</sup> 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

##### Email address

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

##### Province

Isfahan

##### 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 cm<sup>2</sup> 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

#### **City**

Isfahan

#### **Province**

Isfahan

#### **Postal code**

81388 94948

#### **Phone**

+98 31 3345 7670

#### **Email**

Fereydoonabedini@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Avicenna Center of Excellence

##### **Full name of responsible person**

Shaghayegh Haghjooy Javanmard

##### **Street address**

School of Advanced Technologies in Medicine, Isfahan University of Medical Sciences, Hezar Jerib street, Isfahan, Iran

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8174673461

##### **Phone**

+98 31 3792 3851

##### **Email**

amt@mui.ac.ir

##### **Web page address**

<https://amt.mui.ac.ir>

#### **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

**Street address**

School of Dentistry, Isfahan University of Medical Science, Hezar Jarib Street, Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3792 5579

**Email**

razavi@dnt.mui.ac.ir

**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

**Street address**

Imam Musa Kazim Hospital, Kaveh Blvd, Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8138894948

**Phone**

+98 31 3345 7670

**Email**

Fereydoonabedini@yahoo.com

**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

**Street address**

Polymer Group, Chemical Engineering Dept., Isfahan University of Technology, Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8415683111

**Phone**

+98 31 3391 5612

**Email**

saied@iut.ac.ir

**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