

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of dressing with Amniotic membrane and Nitrofurazone ointment in second degree burn wound in THE IMAM KHOMEYNI hospital of URMIA

#### Protocol summary

##### Study aim

The aim of this study was to compare the efficacy of amniotic membrane dressing with nitrofurazone-impregnated dressing in healing second-degree burn

##### Design

The research was conducted as a single-center, double-blind randomized clinical trial (RCT) in Trauma and Burn Center of Imam Khomeini teaching Hospital in Urmia. The main objective of the study was to compare the dressing by amniotic membrane versus nitrofurazone-impregnated gauze in the treatment of second-degree burns among burn patients.

##### Settings and conduct

In the first group, the amniotic membrane donated by the hospital was used to dress the superficial second-degree wound. Petroleum-impregnated gauze and wet gauze were placed on amniotic membrane and bandaged. In the dressing group with nitrofurazone-impregnated gauze, 20 g of ointment per burn percentage was used. Then, relevant variables were collected in a checklist for all patients.

##### Participants/Inclusion and exclusion criteria

The inclusion criterion was presence of superficial second-degree burn

##### Intervention groups

45 patients entered the first group (amniotic membrane dressing) and 42 patients entered the second group (nitrofurazone ointment-impregnated gauze).

##### Main outcome variables

The study endpoints were as follows: extent of wound infection, severity of pain in the dressing site, level of epithelialization, number of days needed for epithelialization of superficial second-degree burn wound as well as hospitalization period, frequency of dressing changes, analgesic use, and wound scarring rate of patients.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181216041996N1**

Registration date: **2019-01-22, 1397/11/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-01-22, 1397/11/02**

Update count: **0**

##### Registration date

2019-01-22, 1397/11/02

##### Registrant information

##### Name

AFSHIN ZAHEDI

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3348 0098

##### Email address

dr.afshinz@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-21, 1397/11/01

##### Expected recruitment end date

2019-05-22, 1398/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of dressing with Amniotic membrane and Nitrofurazone ointment in second degree burn wound in THE IMAM KHOMEYNI hospital of URMIA

## Public title

Comparison of dressing with Amniotic membrane and Nitrofurazone ointment in second degree burn wound

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

superficial second-degree burn in all age groups

### Exclusion criteria:

unstable vital signs, history of psychiatric disorders in patients with burns smoking, drug and psychotropic substance addiction history of heart, kidney, and liver diseases, diabetes, malnutrition, history of corticosteroids or immunosuppressive drugs use, inhalation and old burns evidence of infection in burns reaction and hypersensitivity to nitrofurazone ointment as well as to dressing with amniotic membrane need for wound debridement in operation room non-referral of patients after hospital discharge

## Age

No age limit

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Outcome assessor
- Data analyser

## Sample size

Target sample size: **70**

Actual sample size reached: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

For randomization, the sequences were assigned by an independent researcher using random allocation software version 1 (reference No.21) in permuted blocks of 2 or 4. At the time of randomization, a nurse who was not involved in the study process or care of patients opened a numbered envelope containing patient allocation sheets in one of the two study groups, and the participants were thus assigned to any of the two study groups.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

For blindness, the type of treatment (amniotic membrane and nitrofurazone ointment) was only determined by the first researcher, and the second researcher who was involved in collecting information and completing the checklist had no knowledge of treatment type, prescription, and patient group

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Urmia University of medical sciences

##### Street address

Imam Khomeini Hospital Ershad street

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5715789397

#### Approval date

2018-10-03, 1397/07/11

#### Ethics committee reference number

IR.UMSU.REC.1397.245

## Health conditions studied

### 1

#### Description of health condition studied

superficial second-degree burns

#### ICD-10 code

M61.30

#### ICD-10 code description

Calcification and ossification of muscles associated with burns, unspecified site

## Primary outcomes

### 1

#### Description

wound infection

#### Timepoint

seventh, fourteenth, and thirtieth days

#### Method of measurement

observation . examination

### 2

#### Description

, severity of pain in the dressing site

#### Timepoint

first 7 days

#### Method of measurement

The severity of pain was measured using Visual Analogue Scale 0 to 10 numeric pain distress scale- on which the patient left marks based on their pain sensation

### 3

**Description**

level of epithelialization

**Timepoint**

seventh, fourteenth, and thirtieth days

**Method of measurement**

observation

### 4

**Description**

hospitalization period

**Timepoint**

hospitalization period

**Method of measurement**

observation

### 5

**Description**

frequency of dressing changes

**Timepoint**

first 7 days

**Method of measurement**

observation

### 6

**Description**

analgesic use

**Timepoint**

first 7 days

**Method of measurement**

observation

### 7

**Description**

wound scarring rate

**Timepoint**

seventh, fourteenth, and thirtieth days

**Method of measurement**

Vancouver scar score

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: the amniotic membrane donated by the hospital was used to dress the superficial second-degree wound

**Category**

Treatment - Drugs

### 2

**Description**

Control group: In the dressing group with nitrofurazone-

impregnated gauze, 20 g of ointment per burn percentage was used

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Urmia Imam Khomeini Hospital

**Full name of responsible person**

Afshin Zahedi

**Street address**

Urmia Imam Khomeini Hospital Ershad street

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5715789397

**Phone**

+98 44 3346 9931

**Email**

dr.afshinz@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Afshin Zahedi

**Street address**

Urmia University of Medical Science Resalat Blvd

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5714783734

**Phone**

+98 44 3223 4897

**Email**

dr.afshinz@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Oroumia 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**

Oroumia University of Medical Sciences

**Full name of responsible person**

Afshin Zahedi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Surgery

**Street address**

Urmia Imam Khomeini Hospital Ershad street

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5715789397

**Phone**

+98 44 3346 9931

**Email**

dr.afshinz@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Jafar Kazemzadeh

**Position**

Consultant

**Latest degree**

Subspecialist

**Other areas of specialty/work**

General Surgery

**Street address**

Urmia Imam Khomeini Hospital Ershad street

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5715789397

**Phone**

+98 44 3346 9931

**Email**

jafarkazemzade48@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Afshin Zahedi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Surgery

**Street address**

Urmia Imam Khomeini Hospital Ershad street

**City**

Urmia

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5715789397

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**Email**

dr.afshinz@yahoo.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**

Not applicable

**Informed Consent Form**

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

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable