

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

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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

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

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Position

Consultant

Latest degree

Subspecialist

Other areas of specialty/work

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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

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