

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the effectiveness of biological amniotic membrane dressing with conventional ones in acute burn wounds

Protocol summary

Study aim

Comparison of the effectiveness of biological amniotic membrane dressing with conventional ones in acute burn wounds in Ali-Ebne-Abitaleb hospital in Zahedan

Design

A randomized, blinded, clinical trial with a parallel group design of 100 patients, enrolled between February 2020 and February 2021.

Settings and conduct

The aim of this study is to compare the efficacy of biological amniotic membrane dressing with conventional dressing in acute burn wounds. Patients will be randomly divided into two groups: biological amniotic membrane dressing group and conventional dressing group. In first group, the dressing is from selective cesarean section deliveries in the Ali ibn Abitalib Hospital and in second group, silver sulfadiazine dressing will be used. Patients in both groups will be matched for age, sex and burn percentage. Block randomization with blocks of 10. Considering the sample size of 50, 5 blocks will be selected; in each block there will be equal numbers of cards for each group. By selecting each block, 5 patients in each group will be selected. This is a double blinded study, Patients and outcome evaluator (trained nurse) will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All the patients with skin burn admitted to Ali Ibn Abi Talib Hospital in Zahedan in 2020 Exclusion criteria: Immune system disorder Chronic diseases like : Diabetes Mellitus

Intervention groups

Intervention group 1: biological amniotic membrane dressing Intervention group 2: conventional wound dressing

Main outcome variables

Burn Wound Infection Times of Morphine administration
Duration of hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191102045308N1**

Registration date: **2020-03-11, 1398/12/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-11, 1398/12/21**

Update count: **0**

Registration date

2020-03-11, 1398/12/21

Registrant information

Name

arsalan shirouyeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5576

Email address

dr.arsalanshirovyeh@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-22, 1398/11/02

Expected recruitment end date

2020-04-21, 1399/02/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of biological amniotic membrane dressing with conventional ones in acute burn wounds

Public title

Comparison of the effectiveness of biological amniotic membrane dressing with conventional ones

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All the patients with skin burn admitted to Ali Ibn Abi Talib Hospital in Zahedan in 2020

Exclusion criteria:

Immune system disorder Chronic diseases like : Diabetes Mellitus

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with blocks of 10. Considering the sample size of 50, 5 blocks will be selected; in each block there will be equal numbers of cards for each group. By selecting each block, 5 patients in each group will be selected.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double blinded study, Patients and outcome evaluator (trained nurse) will be blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

khalij fars blv, Ali ebne Abitaleb Hospital

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2018-06-17, 1397/03/27

Ethics committee reference number

IR.ZAUMS.REC.1397.149

Health conditions studied

1

Description of health condition studied

Acute Burns

ICD-10 code

T30

ICD-10 code description

Burn and corrosion, body region unspecified

Primary outcomes

1

Description

Burn Wound Infection

Timepoint

daily

Method of measurement

Based on evidence of burning wound infection

2

Description

Times of Morphine administration

Timepoint

daily

Method of measurement

times

3

Description

Duration of hospitalization

Timepoint

daily

Method of measurement

days

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: biological amniotic membrane dressing

Category

Treatment - Other

2

Description

Intervention group: conventional wound dressing

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-ebn Abi Taleb Hospital, Zahedan

Full name of responsible person

Arsalan Shirouyeh

Street address

Operation room, Zahedan Ali-ebn Abi Talib Hospital,
Salamat Blvd, Dr.Hesabi Sq., Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5570

Email

dr.arsalanshirovyeh@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Nour Mohammad Bakhshani

Street address

Dr Hesabi Sq.

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5744

Email

zaums.research@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Arsalan Shirouyeh

Position

Surgery Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Ali-ebn Abi Talib Hospital, Salamat Blvd, Dr.Hesabi
Sq., Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5570

Email

dr.arsalanshirovyeh@zaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Abdulbaset Maleknejad

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Operation room, Zahedan Ali-ebn Abi Talib Hospital,
Salamat Blvd, Dr.Hesabi Sq., Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5570

Email

dr.arsalanshirovyeh@zaums.ac.ir

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

Zahedan University of Medical Sciences

Full name of responsible person

Arsalan Shirouyeh

Position

Surgery Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Ali-ebn Abi Talib Hospital, Salamat Blvd, Dr.Hesabi Sq., Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5570

Email

dr.arsalanshirovyeh@zaums.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

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