

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

Zahedan University of Medical Sciences

**Full name of responsible person**

Arsalan Shirouyeh

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Surgery Resident

**Latest degree**

Medical doctor

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**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