

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparison of the advantages of the amnion (biological dressing ) + silver sulfadiazine standard dressings in treatment of acute burn wounds of the second deep burn and third degree

#### Protocol summary

##### Study aim

Comparison of the advantages of amnion silvrasulfadiazin with standard dressing

##### Design

Randomized, clinical trial on two groups, blinded, conducted on 50 patients

##### Settings and conduct

A blinded study will be conducted on patients with the second deep and third burn degree in Ahvaz Taleghani Hospital. The dressing is changed in the operation room

##### Participants/Inclusion and exclusion criteria

Patient whit the second deep burn and third degree

##### Intervention groups

One group will be dressed with Amnion membran and silver cream , the other group will be dressed with silver

##### Main outcome variables

Age; sex; number of dressing changes; duration of preparation for graft; number of dressing changes;the effectiveness of two methods; checking the amount of use opium

#### General information

##### Reason for update

##### Acronym

CAA

##### IRCT registration information

IRCT registration number: **IRCT20231202060240N1**

Registration date: **2024-03-02, 1402/12/12**

Registration timing: **retrospective**

Last update: **2024-03-02, 1402/12/12**

Update count: **0**

##### Registration date

2024-03-02, 1402/12/12

##### Registrant information

##### Name

Ali Nazeri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3311 9843

##### Email address

dr.alinazeri@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-28, 1402/08/06

##### Expected recruitment end date

2024-01-27, 1402/11/07

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the advantages of the amnion (biological dressing ) + silver sulfadiazine standard dressings in treatment of acute burn wounds of the second deep burn and third degree

##### Public title

Effect of Amnion dressing in healing of burn wounds

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patient whit acute burn wounds of the second and third

##### Exclusion criteria:

Electrical burn

## Age

From **1 year** old to **80 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Patient does not know the type of dressing

## Placebo

Not used

## Assignment

Parallel

## Other design features

None

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

##### Street address

Hejrat Blvd, Padadshahr, Ahvaz

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6187954386

#### Approval date

2023-10-28, 1402/08/06

#### Ethics committee reference number

IR.AJUMS.REC.1402.392

## Health conditions studied

### 1

#### Description of health condition studied

burn

#### ICD-10 code

T31

#### ICD-10 code description

Burns classified according to extent of body surface involved

## Primary outcomes

### 1

#### Description

Amount of opium

#### Timepoint

At the time of dressing change

#### Method of measurement

Milligram

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: adding amnion membrane to standard dressing that will be changed every three days.

#### Category

Treatment - Surgery

### 2

#### Description

Control group: standard dressing. Silversulfadiazin 1% is used in this group that will be changed every day .

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleghani Hospital

##### Full name of responsible person

Dr. Rahbar

##### Street address

Hejrat Blvd, Padadshahr, Ahvaz

##### City

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61867954386

##### Phone

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##### Email

dr.alinazeri@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr. Rahbar

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**Grant name**

Ahvaz University of Medical Sciences

**Grant code / Reference number**

ندارد

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

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Ali Nazeri

**Position**

Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

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**Latest degree**

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**Other areas of specialty/work**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All information can be shared

**When the data will become available and for how long**

Four months after publication

**To whom data/document is available**

Everyone

**Under which criteria data/document could be used**

Treatment of burnt patient

**From where data/document is obtainable**

My Email address

**What processes are involved for a request to access data/document**

As soon as possible

**Comments**