

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### The effect of Aloe vera gel on healing, pain and itching burn wound

#### Protocol summary

##### Study aim

Effects of Aloe vera Gel on healing pain and itching caused by burn wound

##### Design

Double blind clinical trial with parallel groups, who were selected in simple randomized method using table of random numbers. Final sample size was 34 patients.

##### Settings and conduct

After obtaining permission from research deputy and ethics committee, the study will be conducted in burn units of Sina Medical Education Center. The patients are selected and the treatment objectives and types are introduced. The patients will be unaware of which substance will be used on which region of the body. The wounds will be washed and routine care will be conducted in control group and Aloe vera Gel will be used in intervention group. Heal is measured daily with Bets Jensen inventory and pain and itching are measured 30 minutes before and after bandage during the day and using visual scale (VAS) at night, then the results will be compared for the days 1,3,5,7,9,11,14. Statistical analyzer will proceed on the data analysis without having knowledge of intervention type.

##### Participants/Inclusion and exclusion criteria

Patients with maximum 20% burning of the body surface and first degree burns without blister in the sympathetic organs with the same depth are included in the study. Patients with additional diseases, using substances other than drinking water on the burn are excluded from the study.

##### Intervention groups

Aloe vera Gel is used in intervention group and routine treatment method is used in control group and then they are bandaged

##### Main outcome variables

Healing, Pain, Itching

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160424027561N10**

Registration date: **2018-04-04, 1397/01/15**

Registration timing: **retrospective**

Last update: **2018-04-04, 1397/01/15**

Update count: **0**

##### Registration date

2018-04-04, 1397/01/15

##### Registrant information

###### Name

Mojgan Lotfi

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3479 6770

###### Email address

mlofti@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

University of Medical Sciences

##### Expected recruitment start date

2017-01-19, 1395/10/30

##### Expected recruitment end date

2017-08-21, 1396/05/30

##### Actual recruitment start date

2016-03-19, 1394/12/29

##### Actual recruitment end date

2017-08-21, 1396/05/30

##### Trial completion date

empty

##### Scientific title

The effect of Aloe vera gel on healing, pain and itching burn wound

**Public title**

the effect of Aloe Vera gel on burn wound

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with 20% or less burns First degree and superficial epidermal without blister burns patient with symmetry and same depth burns wound Adults male and female 17-60 years old Common language between therapist and patient for effective communication The patients should have sufficient awareness and consciousness for cooperation Referral to the center 2 hours, at most, after burning Suffering burn due to unintentional

**Exclusion criteria:**

Electrical and chemical burning Patients with inhalation injuries The patient should have background disease history (renal disease, cardiovascular disease, hearing problem, diabetes mellitus, allergic skin disease, malignancy, AIDS). The patient should have history of antis stress and cytotoxic drugs consumption. In case of advent of every kind of unusual side effect such as allergy to Aloe vera or dissatisfaction, the patient is excluded from the study The patient's wound has been smeared into contaminants before patient is included in the study. A substance other than drinking water to be used on the wound before patient is included in the study. The patient should have history of mental illness and referral to psychiatrist

**Age**

From **17 years** old to **80 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**

Target sample size: **34**

More than 1 sample in each individual

Number of samples in each individual: **2**

Regarding sympathetic organs such as left and right hand with burning of the same depth, degree and status, it should be noted that one of the organs is randomly placed in the control and the other one is placed in the intervention group.

Actual sample size reached: **34**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Regarding sympathetic organs such as left and right hand with burning of the same depth, degree and status, it should be noted that one of the organs is randomly placed in the control and the other one is placed in the intervention group.

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Control and intervention groups are selected by simple

random sampling and random numbers table will be used

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study the patients were explained about routine care and Aloe vera in detail, however they will be unaware of which care to be employed for which burnt organ. Moreover, the statistical analyzer will be completely unaware of what data is related to what care.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

**Street address**

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166616471

**Approval date**

2017-01-08, 1395/10/19

**Ethics committee reference number**

IR.TBZMED.REC.1395.1052

**Health conditions studied****1****Description of health condition studied**

Burn

**ICD-10 code**

L55.0, T21

**ICD-10 code description**

burns and corrosions, contact with heat and hot substances

**Primary outcomes****1****Description**

Healing

**Timepoint**

Every day until the 14th day

### Method of measurement

Bates-Jensen wound assessment tool

## 2

### Description

Pain

### Timepoint

Every day 30 minutes before dressing, 30 minutes after dressing and 8 nights until the 14th day

### Method of measurement

Visual analogue scale (VAS)

## 3

### Description

Itching

### Timepoint

Every day 30 minutes before dressing, 30 minutes after dressing and 8 nights until the 14th day

### Method of measurement

Visual analogue scale (VAS)

## Secondary outcomes

empty

## Intervention groups

### 1

### Description

In the intervention group, after washing the wound with water, the Aloe vera gel(94% concentration and 3 mm of thickness ) made in Seagull company is used and then one layer of Vaseline gauze is applied on it in order to prevent gel evaporation and it is bandaged, at last

### Category

Treatment - Drugs

### 2

### Description

In the control group, on the other hand, after washing the wound with water, the routine treatment in the unit (1% Silver sulfadiazine made in Sobhan Darou Pharmacy Company) with thickness of 3 mm is used and then the pomade surface is covered with one layer of Vaseline gauze to prevent its evaporation and finally it is bandaged.

### Category

Treatment - Drugs

## Recruitment centers

### 1

### Recruitment center

#### Name of recruitment center

Sina Teaching Hospital

#### Full name of responsible person

maryam mahboob

#### Street address

Children Hospital, Sheshgelan Street, Tabriz

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## Sponsors / Funding sources

### 1

### Sponsor

#### Name of organization / entity

Vice chancellor for Research, Tabriz University Of Medical Sciences

#### Full name of responsible person

Abolghasem Jouyban

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Daneshgah Street,Tabriz

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#### Postal code

5166616471

#### Email

Ravabetomomi@tbzmed.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice chancellor for Research, Tabriz 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

Tabriz University of Medical Sciences

#### Full name of responsible person

Zahra Sheikh Alipour

#### Position

Candidate for Ph.D Nursing

#### Latest degree

Master  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**Web page address**

## 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

Only the results presented by the scholar are applicable without analysis.

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

Access time 1 months after the results are published

### To whom data/document is available

All faculty members of medical science universities.

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

Only the results presented by the scholar are applicable without analysis.

### From where data/document is obtainable

Data are available upon receive of mail by the scholar.  
Mojgan Lotfi, 00989144130632, mlotfi@tbzmed.ac.ir  
Maryam Mahboob, 00989143098494,  
artsport2000@gmail.com

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

The scholar will be accessible, instantly, through email and then the requested files will be sent.

### Comments