Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

" Study of the effectiveness of Bilva ointment on burn wound outcomes of patients admitted "

Protocol summary

Study aim
Determine the Effectiveness of Bilva Ointment on the Outcome of Burn Sores

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
The burn wards of men and women located in Sina Hospital will be considered as the research environment. First, qualified individuals will be included in the study after obtaining informed consent. Member (right or left) in the intervention group is determined by random numbers and stored in envelopes. These packs are determined by specimens without the intervention of the researcher and consequently by random allocation.

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
An organ burned with silver sulfadiazine ointment 1% will be dressed in accordance with the routine of the hospital and its sympathetic section using Beiloy ointment. Other nursing care such as daily bath, primary wound healing with normal saline before dressing, management of blister wounds and ... will be the same for both members.

Main outcome variables
Wound healing,Pain,Itching,Infection,Hypertrophy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160424027561N11**
Registration date: **2018-08-30, 1397/06/08**
Registration timing: **retrospective**

Last update: **2018-08-30, 1397/06/08**
Update count: **0**

Registration date
2018-08-30, 1397/06/08

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
mlotfi@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-03-20, 1395/12/30

Expected recruitment end date
2018-06-20, 1397/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
" Study of the effectiveness of Bilva ointment on burn wound outcomes of patients admitted "

Public title

" Study of the effectiveness of Bilva ointment on burn wound outcomes of patients admitted"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with 20% or less burns of second degree The location of the burn in the symetric extremities with the same depth Patients who do not have any underlying disease such as diabetes mellitus, allergic skin diseases, malignancy, AIDS, hypertension, and cytotoxic drugs. It is not more than 2 hours from the time of burning up to the time of entry into the research The patient's wound is not impregnated with contaminants The patient did not use any substance other than drinking water on the wound before the sample entered the study Before entering the study, the patient is not infected with different parts of the body The patient is able to answer questions.

Exclusion criteria:

The cause of the patient's burn is chemical or electrical. Patients who have inhaling injuries

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **33**

More than 1 sample in each individual

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

Both sides of symmetrical wounds, one is in the control group and the other is in the intervention group.

Randomization (investigator's opinion)

Randomized

Randomization description

First, patients are selected based on entry criteria. A random number table is used to select which hand (right or left) is in the control or intervention group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The person completing the checklist is not aware of the type of treatment has undergone. An analyst is not aware of the type of the group.

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, University Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2017-06-12, 1396/03/22

Ethics committee reference number

IR.TBZMED.REC.1396.227

Health conditions studied

1

Description of health condition studied

burn wound outcomes of patients admitted

ICD-10 code

T22.6

ICD-10 code description

Corrosion of second degree of shoulder and upper limb, except wrist and hand

Primary outcomes

1

Description

burn wound healing score

Timepoint

Day one, seventh, fourteenth, twenty eight, one month later, two months later, three months later

Method of measurement

Bates-Jensen wound assessment tool

2

Description

pain

Timepoint

Day one, seventh, fourteenth, twenty eight, one month later, two months later, three months later

Method of measurement

Visual analogue scale (VAS)

3

Description

Itching

Timepoint

Day one, seventh, fourteenth, twenty eight, one month later, two months later, three months later

Method of measurement

itching Visual analogue scale (VAS)

4

Description

infection

Timepoint

Day one, seventh, fourteenth, twenty eight, one month later, two months later, three months later

Method of measurement

questionnaire

5

Description

Hypertrophy of scar

Timepoint

one month later, two months later, three months later

Method of measurement

Vancouver questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, after washing the wound with water, the Bilva ointment made in Tabnak company is used and then it is bandaged.

Category

Treatment - Drugs

2

Description

Control group: In the control group, after washing the wound with water, the routine treatment in the unit, 1% Silver sulfadiazine made in Sobhan Darou Pharmacy Company, 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 Hospital

Full name of responsible person

Safa Tabnak

Street address

5th Floor, 10th Floor, 10th Meter Second West, First Park, North Tavanir

City

Tabriz

Province

East Azarbaijan

Postal code

5156964946

Phone

+98 41 3328 2085

Email

Tabnaktebco@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Reza Rashidian

Street address

Daneshgah Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3479 6770

Email

nursing@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Mojghan Lotfi

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work
Nursery
Street address
Nursing collage, South Shariatee
City
Tabriz
Province
East Azarbaijan
Postal code
5156964946
Phone
+98 41 3328 2085
Fax
+98 41 3479 0365
Email
lotfim@tbzmed.ac.ir
Web page address
https://nursing.tbzmed.ac.ir/

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Elnaz Asghari
Position
Consultant
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Faculty of Nursing and Midwifery .Shriati Street. tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3478 0653
Fax
+98 41 3478 0653
Email
asghariel@tbzmed.ac.ir
Web page address
https://nursing.tbzmed.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Safa Tabnak
Position
nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Nursing and midwifery collage, South Shariatee
City
Tabriz
Province
East Azarbaijan
Postal code
5156964946
Phone
+98 41 3328 2085
Email
Tabnaktebco@gmail.com

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.
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Data are available upon receive of mail by the scholar. Mojgan Lotfi, 00989144130632, mlotfi@tbzmed.ac.ir
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
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