

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Comparative study of combined the effect of Cucurbita pepo L. oil and 1% silver sulfadiazine ointment with the control group on wound healing and severity of second degree burn pain in children 2-7 years

#### Protocol summary

##### Study aim

Determining the combined the effect of Cucurbita pepo L. oil and 1% silver sulfadiazine ointment with the control group on wound healing and severity of second degree burn pain in children 2-7 years

##### Design

The current research is a clinical trial study with a control group, with parallel groups, double-blind, random allocation, phase 3 on 98 eligible patients, who will be divided into two intervention and control groups using the random allocation (block) method.

##### Settings and conduct

This research is conducted on eligible children aged 2-7 years with second degree burns hospitalized in the burn department of Ayatollah Kashani Educational-Treatment Center, Shahrekord University of Medical Sciences, in compliance with all ethical conditions. Before the intervention, questionnaires are completed by all samples. In the intervention group, for the preparation of pumpkin seed oil, prepared Cucurbita pepo L. oil from Zardband company will be used, which is consistent with the mentioned study method and approved by the Ministry of Health. For the control group, 1% silver sulfadiazine ointment will be provided from the reputable Sina Daru company in the form of 50 gram tubes. In this study, patients, researchers, nurses and the person responsible for the analysis will not know the type of intervention for each person or group.

##### Participants/Inclusion and exclusion criteria

Children with second degree burns, 2 to 7 years old

##### Intervention groups

The studied patients are bandaged with pumpkin seed oil and silver sulfadiazine 1% once a day for a period of 14 days. The experimental group is treated with Cucurbita pepo L. oil and the control group is treated only with 1% silver sulfadiazine.

##### Main outcome variables

Face, Legs, Activity, Cry, Consolability scale is used to evaluate pain and Bates-Jensen Wound Assessment Tool is used to evaluate degeneration or healing of burn wounds.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190120042436N5**

Registration date: **2023-01-29, 1401/11/09**

Registration timing: **prospective**

Last update: **2023-01-29, 1401/11/09**

Update count: **0**

##### Registration date

2023-01-29, 1401/11/09

##### Registrant information

##### Name

Mohsen Salari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 3323 4115

##### Email address

salarimo@yums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-09, 1401/11/20

##### Expected recruitment end date

2023-06-10, 1402/03/20

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparative study of combined the effect of Cucurbita pepo L. oil and 1% silver sulfadiazine ointment with the control group on wound healing and severity of second degree burn pain in children 2-7 years

**Public title**  
Comparative study of combined the effect of Cucurbita pepo L. oil and 1% silver sulfadiazine ointment on wound healing and severity of second degree burn pain

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
The cause of thermal burns Consent to participate in the study Age 2 to 7 years Second degree burn and below 20% and thermal type Burns in the hands and feet except the fingers Do not wash excessively with water and detergents Not having diseases that weaken the immune system The child's face is healthy and does not suffer from any congenital malformation, especially in the organs and face, and does not have trauma in the organs  
**Exclusion criteria:**  
Lack of parental consent Creating an active infection at the site of the lesion Use of topical immunosuppressants within four weeks before starting treatment Local infection Any vascular disease of the brain, cardiovascular Patients needing a skin graft for treatment

**Age**  
From **2 years** old to **7 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **98**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Eligible children are selected through non-probability (available) sampling, but they are assigned to one of the two groups of intervention exercises and the control group in the form of random block allocation. The random allocation of blocks will be in such a way that according to the number of studied groups, which consists of two groups consisting of group 1 (intervention) and group 2 (control), the number of

blocks will be calculated based on the factorial law, that is,  $2 = 1 * 2 = 2!$ . The possible arrangement modes of the participants from each group in each block are indicated by the label A representing group 1 (intervention), B representing group 2 (control). Therefore, there are 2 blocks for random allocation, where there are 2 participants in each block, one person from each group, but their order is different. Block sampling will continue until the number of samples is completed. It should be noted that since there are 2 samples in each block, the number of selected samples will be the same in both groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, the patients are informed that they may be placed in one of the intervention or control groups, and naturally they will receive the medicine related to the same group. In addition, the main researcher and the nurse who is responsible for the care of the patients, the person responsible for collecting the data and those who evaluate the outcome and the person responsible for the analysis will not know the type of intervention for each person or group.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Research Ethics Committees of Yasuj University of Medical Science

**Street address**

Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad Province

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyerahmad

**Postal code**

7591741417

**Approval date**

2023-01-04, 1401/10/14

**Ethics committee reference number**

IR.YUMS.REC.1401.161

**Health conditions studied**

**1**

**Description of health condition studied**

Burn of second degree

**ICD-10 code**

T30.2

**ICD-10 code description**

Burn of second degree, body region unspecified

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

Wound healing score of Bates-Jensen Wound Assessment Tool

**Timepoint**

The first session before the start of treatment, the third day, the seventh day and the day of the clear start of epithelization, the day of repair and the fourteenth day after the start of treatment

**Method of measurement**

Bates-Jensen Wound Assessment Tool for healing of burn

**2****Description**

pain severity

**Timepoint**

The first session before the start of treatment, the third day, the seventh day and the day of the clear start of epithelization, the day of repair and the fourteenth day after the start of treatment

**Method of measurement**

Face, Legs, Activity, Cry, Consolability scale (FLACC scale)

**Secondary outcomes****1****Description**

pain degeneration

**Timepoint**

The first session before the start of treatment, the third day, the seventh day and the day of the clear start of epithelization, the day of repair and the fourteenth day after the start of treatment

**Method of measurement**

Bates-Jensen Wound Assessment Tool

**Intervention groups****1****Description**

Intervention group: The studied patients are dressed with pumpkin seed oil by the researcher once a day for a period of 14 days. The experimental group is treated with pumpkin seed oil. In this way, after washing the wounds daily with normal saline, in second-degree superficial wounds that usually have a complete blister, without removing the blister in the experimental group, a layer of pumpkin seed oil with a diameter of 5 mm will be placed on the wound and it is a dressing. In a second degree deep wound where the blisters are usually

destroyed, after removing the blisters and dead tissues and washing the wound surface with normal saline in a sterile way and placing a layer of pumpkin seed oil with a diameter of 5 mm on the wound, a bandage is applied. be made patients in six stages; The first session before the start of treatment, the third day, the seventh day and the day of the clear start of epithelization, the day of recovery and the fourteenth day after the start of treatment are evaluated, and the day of the clear start of epithelization and the start of the repair process will be recorded for each patient. To check the condition of the wound, they are evaluated during the study and every time the dressing is changed. If any of the samples stop participating in the research for some reason, they will be removed and other samples will be selected and replaced in their place. Also, the condition of the wound is checked for the presence of granulation tissue and epithelization every time the dressing is changed. If signs of infection are observed, the sample will be removed from the study and referred to the doctor for further treatment. In order to increase the accuracy and accuracy of the research, two observers (the researcher and the permanent nurse who changes the dressing) will be used before the study and compared in the observed position. In addition, in each session, with the consent of the patient, photographs are taken of the lesions and they are examined in terms of the healing process. In this study, patients, caregivers, researchers and the person responsible for the analysis will not know the type of intervention for each person or group.

**Category**

Treatment - Drugs

**2****Description**

Control group: The studied patients were dressed with 1% silver sulfadiazine by the researcher once a day for a period of 14 days. The control group is treated only with 1% silver sulfadiazine. In this way, after washing the wounds daily with normal saline, in second-degree superficial wounds that usually have a complete blister, without removing the blister in the control group, a layer of 1% silver sulfadiazine cream with a diameter of 5 mm will be placed on the wound. And it is bandaged. In a second degree deep wound where the blisters are usually destroyed, after removing the blisters and dead tissues and washing the wound surface with normal saline in a sterile way and placing a layer of pumpkin seed oil with a diameter of 5 mm on the wound, a bandage is applied. be made patients in six stages; The first session before the start of treatment, the third day, the seventh day and the day of the clear start of epithelization, the day of recovery and the fourteenth day after the start of treatment are evaluated, and the day of the clear start of epithelization and the start of the repair process will be recorded for each patient. To check the condition of the wound, they are evaluated during the study and every time the dressing is changed. If any of the samples stop participating in the research for some reason, they will be removed and other samples will be selected and replaced in their place. Also, the condition of the wound is checked for the presence of

granulation tissue and epithelization every time the dressing is changed. If signs of infection are observed, the sample will be removed from the study and referred to the doctor for further treatment. In order to increase the accuracy and accuracy of the research, two observers (researcher and a permanent nurse changing the dressing) will be checked and compared before the study, in the observed position. In addition, in each session, with the consent of the patient, photographs are taken of the lesions and they are examined in terms of the healing process. In this study, patients, researchers, nurses and the person responsible for the analysis will not know the type of intervention for each person or group.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ayatollah Kashani hospital

**Full name of responsible person**

Maede Barati

**Street address**

Nurse Street., Ayatollah Kashani Hospital

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

۸۸۱۶۷۵۸۹۱۵

**Phone**

+98 38 3226 4825

**Email**

m.barati7788@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Seyed Amin Hossaini Motlagh

**Street address**

Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad Province

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyerahmad

**Postal code**

7591741417

**Phone**

+98 74 3333 7230

**Email**

m.barati7788@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Yasouj 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**

Yasouj University of Medical Sciences

**Full name of responsible person**

Mohsen Salari

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Yasuj, next to Imam Sajjad Hospital, Educational Campus, nursing Faculty

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyerahmad

**Postal code**

7591755418

**Phone**

+98 74 3323 4115

**Fax**

+98 74 3323 4115

**Email**

salarimo@yahoo.com

**Web page address**

[https://scholar.google.com/citations?user=\\_YWhDEAAA&hl=fa&oi=ao](https://scholar.google.com/citations?user=_YWhDEAAA&hl=fa&oi=ao)

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Hosein Sadeghi

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Yasuj, next to Imam Sajjad Hospital, Educational Campus - Faculty of Medicine

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyerahmad

**Postal code**

7591755418

**Phone**

+98 74 3323 0290

**Fax**

+98 74 3323 0290

**Email**

doctor.sadeghi@gmail.com

**Web page address**

<https://scholar.google.com/citations?hl=fa&user=JiyQ8OIAAAAJ>

**Postal code**

7591755418

**Phone**

+98 74 3323 4115

**Email**

m.barati7788@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**

Part of the data related to the main outcome will be shared

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

Access to data six months after completion of collection and results

**To whom data/document is available**

Access to data through academic institutions

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

Research works and references

**From where data/document is obtainable**

Yasuj University of Medical Science, Faculty of Nursing

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

Access after going through the relevant administrative procedures

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

Yasuj University of Medical Sciences

**Full name of responsible person**

Maedeh Barati

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Shahid Dr. Jalil St., Yasouj University of Medical Sciences, Faculty of Nursing

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyerahmad