

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of Cold Pack Therapy on burn pruritus

Protocol summary

Study aim

The effect of ice bag on itching after burn

Design

This study is a clinical trial in which 64 eligible patients who meet the inclusion criteria are selected through purposive sampling. They will then be randomly assigned to block A and B in both groups. In both groups, patients will be closed daily for twenty minutes after dressing for 5 minutes at a 10- 5 cm gel pack above the most itchy burn site. Be. This study was a double blind study.

Settings and conduct

This study will be carried out in the burn ward of Valiasr Hospital in Arak. Each day after dressing in both groups, patients will be closed for 20 minutes with a 5 to 10 cm high gel pack over the most itchy burn site. Then, the severity of itching will be measured every day before dressing, 30 minutes after intervention and for one week each night using the VAS scale and written in a checklist for each patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having grade 2 superficial burns; having itching in the last 24 hours; ages 18 to 65 years; at least 3 days past the burn; obtaining informed consent from the patient or the patient's family; having no discomfort or sensitivity. Cold, lack of endocrine, metabolic and cardiovascular diseases; lack of allergies and use of anti allergic drugs. Exclusion criteria: patient or family dissatisfaction with continuing to co-operate; discharge, or transfer patient until completion of cold therapy; unbearable distress caused by cold therapy.

Intervention groups

In this study, patients will be randomly divided into two groups: A and B. In group A the cooling gel pack is at ambient temperature and in group B is placed in the freezer for 2 hours.

Main outcome variables

The use of cryotherapy in burn wound care program reduces itching and consequently reduces the damage and its complications such as reduced quality of life, sleep disorder, anxiety and etc in burn patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191024045228N1**

Registration date: **2019-11-28, 1398/09/07**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-28, 1398/09/07**

Update count: **0**

Registration date

2019-11-28, 1398/09/07

Registrant information

Name

Maliheh Abedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 4624 3016

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-03, 1398/07/11

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Cold Pack Therapy on burn pruritus

Public title

The effect of Cold Pack Therapy on burn pruritus

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having grade 2 superficial burns on the organs Itching in the last 24 hours At least 3 days have passed since the patient's burn No feeling of discomfort or sensitivity to cold Lack of endocrine, metabolic and cardiovascular diseases (liver and kidney failure, diabetes, etc.) Not having allergies and taking allergy medications Obtaining informed consent from the patient or the patient's family

Exclusion criteria:

Patient or family dissatisfaction with continuing cooperation Discharge or transfer of the patient before the end of the period of Cold Therapy Unbearable discomfort caused by Cold Therapy for the patient

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were divided into four groups A and B in a randomized block design.

Blinding (investigator's opinion)

Double blinded

Blinding description

In both groups, patients were closed 5–10 cm above the burn site with the most itching for 20 minutes each day after dressing. Except that the cooling gel pack in group A (control) is ambient temperature and in group B (intervention) refrigerated for 2 hours. The researcher and study participants are unaware of group assignment, and the clinician is aware of group assignment.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Third Floor, blue Wing, Payambar aazam (SAW) University Complex, Basij SQ, Sardasht region

City

Arak

Province

Markazi

Postal code

6941-7-38481

Approval date

2019-10-13, 1398/07/21

Ethics committee reference number

IR.ARAKMU.REC.1398.167

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

Second degree burn wound

ICD-10 code

T30.2

ICD-10 code description

Burn of second degree, body region unspecified

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

Burn Pruritus

Timepoint

Before dressing, 30 minutes after intervention (50 minutes after dressing) and every night for one week

Method of measurement

Visual analog scale

Secondary outcomes

empty

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

Intervention group: for patients, after daily dressing for 20 minutes, the gel pack is closed 5 to 10 cm above the burn site with the most itching. The severity of itching was measured every day before dressing, 30 minutes after intervention (50 minutes after dressing), and each night using a VAS scale for one week and recorded in the patient checklist.

Category

Rehabilitation

2**Description**

Control group: in this group, the patients are closed daily

for a period of twenty minutes after gel packing at a temperature of 5-10 cm above the most itchy burn site. The severity of itching was measured every day before dressing, 30 minutes after intervention (50 minutes after dressing), and each night using a VAS scale for one week and recorded in the patient checklist.

Category

Placebo

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

Burn section of Valiasr hospital

Full name of responsible person

Maliheh Abedi

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Hazrat Valiasr Square, Hazrat Valiasr Training Center

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

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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

Yes

Title of funding source

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Maliheh Abedi

Position

MSc Student of Critical Care Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

Arak University of Medical Sciences

Full name of responsible person

Kobra Rahzani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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Other areas of specialty/work
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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