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)

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+98 86 4624 3016

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ma.abedi@arakmu.ac.ir

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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Web page address
https://arakmu.ac.ir/valiasrhos/fa

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
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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