

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of Early Replacement of Skin graft Dressing on Pain and Anxiety in Burn Patients

Protocol summary

Study aim

Reducing the pain caused by dressing in burn patients, reducing the anxiety of dressing in burn patients, reducing hospitalization time and costs for burn patients.

Design

The clinical trial, community-based, include control group, with parallel groups, randomized

Settings and conduct

This randomized clinical trial was conducted on 60 patients aged 18-60 years old admitted to the burn ward of Shahid Rajaei Hospital in Qazvin

Participants/Inclusion and exclusion criteria

Patients entered the study who were undergoing graft surgery; have the ability to speak; dressed in the usual dressing method; do not have known psychological disorders in the past or present; their graft should not be located in the head and neck; do not have neurological disorders and anesthesia in burn limb; do not have severe hearing or visual problems. People who did not have any entry requirements were not included in the study.

Intervention groups

In the intervention group the day after the graft, anesthetic anxiety burning questionnaire was completed and then the dressing would be opened by the researcher. The visual analogue pain questionnaire will be completed during dressing. In both groups, 5 mg of morphine was sacrificed half an hour before changing muscle dressing Will be injected. In the control group, the dressings will be opened and replaced by the researcher three days after the grafting. In the control group, the anxiety inventory of the burn pain will be completed before dressing and the visual pain test during the dressing.

Main outcome variables

Pain; anxiety; time of hospitalization; costs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180926041141N1**

Registration date: **2018-10-24, 1397/08/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-24, 1397/08/02**

Update count: **0**

Registration date

2018-10-24, 1397/08/02

Registrant information

Name

abbas ahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3368 1571

Email address

a.ahmadi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Early Replacement of Skin graft Dressing on Pain and Anxiety in Burn Patients

Public title

The effect of early replacement of the skin graft dressing in the burn

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The patient can speak Dress with an usual method Not having known mental disorders Not having neurological disorders and anesthesia in burned limb Not having severe hearing or visual problems

Exclusion criteria:

The patient can not speak Dress with an unusual method Known mental or psychiatric disorders graft on the head and neck Neurological disorder in burnt limb Severe hearing impairment or visual problem

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The first specimen was stacked and randomly placed in one of the groups. Subsequently, the other specimens were placed in each group by minimization.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Shahid Bahonar Blvd., Qazvin, Iran

City

Qazvin

Province

Qazvin

Postal code

3419915315

Approval date

2017-12-14, 1396/09/23

Ethics committee reference number

IR.QUMS.REC.1396.341

Health conditions studied

1

Description of health condition studied

diseases of skin and subcutaneous

ICD-10 code

اختلال در

ICD-10 code description

اختلال در پوست و بافت زیرجلدی

Primary outcomes

1

Description

Pain score in visual pain scale

Timepoint

Measuring pain one and three days after skin graft

Method of measurement

visual pain scale

2

Description

Anxiety scores in Burn specific pain anxiety scale

Timepoint

Measuring Anxiety of pain one and three days after skin graft

Method of measurement

Burn specific pain anxiety scale

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, dressing will be done 24 hours after skin grafting

Category

Prevention

2

Description

In the control group, the dressing of the skin graft will be done three days after skin grafting

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie Hospital بیمارستان شهید رجایی

Full name of responsible person

Abbas Ahmadi

Street address

Rajaie Hospita, Qarani ave., Padegan street

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Peymani Amir

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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

Qazvin University of Medical Sciences

Proportion provided by this source

10

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

Qazvin University of Medical Sciences

Full name of responsible person

Abbas Ahmadi

Position

nursing student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Leili Yeke Fallah

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

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

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Full name of responsible person

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Position

nursing student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

Unidentifiable individual data is available to publishers

When the data will become available and for how long

One year

To whom data/document is available

Researchers working in collegiate academia and scientific academia

Under which criteria data/document could be used

Any required scientific analysis is allowed

From where data/document is obtainable

abbasahmadi54321@gmail.com

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

The purpose and application of the requested information is to be sent to the e-mail address

Comments