Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Rajaee 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 haveknown 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 subcotaneus
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 Hospitalبیمارستان شهید رجایی

Full name of responsible person
Abbas Ahmadi

Street address
Rajaie Hospita, Qarani ave., Padegan street

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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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rajaie hospital-qarani ave.padegan ave

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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

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Full name of responsible person

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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