Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Breathing Technique Training Effectiveness on Pain Control in Outpatients During Burn Care

Protocol summary

Study aim

The research aims is investigating the effect of pain control through relaxed breathing Technique in patients referring to Burn Clinic of Rasht during burn dressing procedure.

Design

A randomized controlled clinical trial with parallel groups, without blinding, will be conducted for 62 patients. Random Allocation Software will be employed for randomization.

Settings and conduct

All patients who referred to Velayat Burn Center of Rasht will be included in the study provided that they meet the selection criteria, The sampling will be performed based on the gradual referral of patients to the center. The patients assignment to 2 groups of A (receiving breathing training) and B (receiving routine burn care) will be based on their conformity with selection criteria, the 4- Block Randomization procedure, and the order determined through Random Allocation Software prior to the beginning of the study. The list, of patients, will be kept in sealed envelope in the Burn Research Center or the Nursing Office to be read daily and in orderly manner at the beginning of the study.

Participants/Inclusion and exclusion criteria

The participants with second-degree burns and above 15 years of age, will join the study after obtaining their informed consent. The patients with neuropathic symptoms, use of narcotics, inability to communicate pain intensity, chemical and electrical burns, burns extending over more than one anatomical areas and those hospitalized for burn severity will be excluded from the study.

Intervention groups

Patients suffering from second-degree burns with no neuropathic symptoms who seek dressing change in Burn Clinic of Rasht in 2020 will be included in the study.

Main outcome variables

The severity of pain in burned surface area of both groups will be assessed using the Visual Analogue Scale (VAS). Also, the Burn Specific Pain Anxiety Scale, will be employed to assess pain anxiety.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210424051062N1**
Registration date: **2021-06-07, 1400/03/17**
Registration timing: **retrospective**

Last update: **2021-06-07, 1400/03/17**
Update count: **0**

Registration date

2021-06-07, 1400/03/17

Registrant information

Name

Naghmeh Bozorgnia

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 13 3333 3448

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-26, 1400/02/06

Expected recruitment end date

2021-05-27, 1400/03/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Breathing Technique Training Effectiveness on Pain Control in Outpatients During Burn Care

Public title

Breathing Technique Training Effectiveness on Pain Control in Outpatients During Burn Care

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The participants' consent to join the research The participants must be over 15 years old. The participants' TBSA should be less than 20. The participant have a second degree burns.

Exclusion criteria:

Neuropathic symptoms Use of narcotics before referring to burn clinic Inability to communicate pain intensity Non-chemical burn Non-electrical burn Burn extending over more than one anatomical regions Burns leading to hospitalization Inability to learn and use technique

Age

From **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **31**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants will be randomly assigned to respective groups following the 4- block randomization procedure. The list will be kept in a sealed envelope in the Burn Research Center or the Nursing Office to be read daily and in an orderly manner at the beginning of the study.

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

Medical Ethics Committee of Guilan University of Medical Sciences

Street address

Shahid Siadati St., Namjoo Street, Rasht

City

Rasht

Province

Guilan

Postal code

4144654379

Approval date

2021-02-03, 1399/11/15

Ethics committee reference number

IR.GUMS.REC.1399.568

Health conditions studied

1

Description of health condition studied

Burn of second degree, body region unspecified

ICD-10 code

T30.2

ICD-10 code description

Burn of second degree, body region unspecified

Primary outcomes

1

Description

Intensity of pain

Timepoint

Before and after training

Method of measurement

It will be evaluated using visual analog scale (VAS)

2

Description

Anxiety caused by pain

Timepoint

Before and after training

Method of measurement

The Burn Specific Pain Anxiety Scale will be used to assess the level of anxiety caused by patients' pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Initially, the patients' pain intensity will be assessed employing the Visual Analogue Scale (VAS) by a research team member before starting dressing. The patient will exercise the breathing Technique 5 times during 10-minute dressing care. The pain intensity will be reassessed upon redressing the

burn region. The patients, then, will be asked to express the degree of their satisfaction with the burn care procedure in terms of “full satisfaction’, Partial satisfaction” and “dissatisfaction”. The responses will be recorded in the data collection form. The patients with a VAS rate above 3 after the intervention, will be prescribed nonsteroidal anti-inflammatory drugs or acetaminophen as analgesics at the discretion of the physician and the patients' conditions.

Category
Behavior

2

Description
Control group: Control group receives routine burn care

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Velayat burning and reconstructive surgery sub-specialty center

Full name of responsible person
Mohammad Reza Mobayen

Street address
Velayat Hospital, Namjoo St.

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4193713191

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velayathospital@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
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research@gums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Mohammad Reza Mobayen

Position
Assistant Professor of Burn Surgery

Latest degree
Subspecialist

Other areas of specialty/work
General Surgery

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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Naghmeh bozorgnia
Position
General Practitioner
Latest degree
Medical doctor
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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