# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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)

**Phone**

+98 13 3333 3448

**Email address**

n.bozorgnia@yahoo.com

**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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Rasht

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**Postal code**
4193713191

**Phone**
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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**
Mohammad Reza Naghipour

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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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## Person responsible for updating data

**Contact**
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Rasht University of Medical Sciences
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Naghmeh bozorgnia
**Position**
General Practitioner
**Latest degree**
Medical doctor
**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