

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Effect of range of motion exercises on burnt patients' daily activities and quality of life

Protocol summary

Study aim

Determine the effect of range of motion exercises on activity of daily living and quality of life patient with burn

Design

In this research, 60 burn patients referring to Taleghani hospital are selected according to inclusion criteria. participants will be randomly divided into two control and intervention groups.

Settings and conduct

This study is a clinical trial in the field of rehabilitation and done for burn patients in Taleghani hospital of Ahvaz. The study population includes patients with confirmed diagnosis of grade II burns. The sample are randomly assigned to two groups Intervention and control (30 persons).

Participants/Inclusion and exclusion criteria

Inclusion criteria is, second degree burns less than 40%, age between 18 to 60 years, and stable vital signs. patients who needed graft surgery are excluded of study.

Intervention groups

The Barthel's questionnaire and quality of life questionnaire were completed by two group one day prior to the intervention. The control group receives the routine care program at the hospital. Patients in the intervention group, in addition to the routine care program, performed range of motion exercises for 4 weeks, 3 times a day, each movement ten times, each time for 30 second in upper and lower extremities of burnt areas. Barthel's questionnaire will be completed after 4 weeks, and quality of life questionnaire will be completed after three months by patients in both groups.

Main outcome variables

Activities of daily living; Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170709034968N1**

Registration date: **2018-01-22, 1396/11/02**

Registration timing: **retrospective**

Last update: **2018-01-22, 1396/11/02**

Update count: **0**

Registration date

2018-01-22, 1396/11/02

Registrant information

Name

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Name of organization / entity

Jundishapur University of Medical Sciences Ahvaz

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of JundiShapour Ahvaz University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2017-12-31, 1396/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of range of motion exercises on burnt patients' daily activities and quality of life

Public title

The effect of range of motion exercises on activities of daily living and quality of life

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Second degree burn less than 40% age range 18 to 60 years 48 hours have passed since burn injury. No history of neurological and articular problems having no contracture and deformity in joints. having no mental disease or mental retardation. having stable vital signs.

Exclusion criteria:

Patients who need graft surgery during the study.
Patients who have unstable vital signs.

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

Samples are divided randomly bloked (6 Bloks) into 2 control and intervention groups.

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 Ahvaz Jundishapur University of Medical Sciences

Street address

Deputy of Development and Research, Jundishapur University of Medical Sciences

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Postal code

61357-15794

Approval date

2017-06-17, 1396/03/27

Ethics committee reference number

IR.AJUMS.REC. 1396. 319

Health conditions studied**1****Description of health condition studied**

Burn

ICD-10 code

T20, T21

ICD-10 code description

Burns and corrosions of external body surface, specified by site

Primary outcomes**1****Description**

The Score of Activities of daily living in Bartlett's Questionnaire

Timepoint

Before intervention, one month after the intervention

Method of measurement

Bartel questionnaire: Bartel index includes 10 questions with likert scale (0-15) so the scores range is (0-100), questions related to (0-10) scores for eating, (0-5) scores for bathing, (0-5) scores for personal hygiene, (0-10) scores for getting dressed, (0-10) scores for urine control, (0-10) scores for stool control, (0-10) scores for using the toilet, (0-15) scores for transferring from bed to chair and vice versa, (0-15) scores for mobility on flat surfaces and (0-10) scores for using the stairs. The score of 100 shows total independency and the score of 0 shows absolute dependence of the individual for his/her daily activities.

2**Description**

The Score of Quality of Life Questionnaire

Timepoint

Before the intervention, Three months after the intervention

Method of measurement

Burn Specific Health Scale questionnaire: This questionnaire consists of 40 questions with 5 choices of severe, many, average, few and never which are ranked from 1 to 5 respectively. So each question has the minimum score of 1 and the maximum of 5. 18 questions of this questionnaire is for physical dimension of quality of life (minimum 18 scores and maximum 200) , 11 questions for Psychological dimension and 11 questions for Social dimension (minimum 11 scores and maximum 55). With this questionnaire the quality of life is assessed for each dimension separately and also in all of the dimensions. Because the quality of life is based on the scores' average, the higher the mean, the better the quality of life and the lower mean represents lower quality of life.

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group: The Persian version of Burn Specific Health Scale (BSHS) and the Barthel's daily life activities questionnaire will be given to patients one day before beginning the intervention. Required explanations about how to fill in this questionnaire will also be given to all patients in the same way. In addition to care routine program, patients will go under the range of motion exercises described in this study. So all patients of intervention group will receive scheduled range of motion exercises for 4 weeks, 3 times a day, 10 sets for each movement and each set 30 seconds in each injured upper and lower limb and completely controlled (patient should perform the movements in a way which is not rapidly and uncontrollable and perform these exercises in all range of joints and slowly and be able to stop the movement in each part of range of motion if needed) depending on whether the upper limb or the lower limb is burned. These exercises will be performed on the wrists, elbows and shoulders joints in the upper limbs and the ankle and knee and thigh joints in the lower extremities. Movements will be performed in the full range of the joint, with maximum bending- straightening of joint, maximum range of abducting-adducting and maximum range of spin-to-inside and spin-to-out if possible. Exercises consist of bending and straightening in the elbow joint; bending-straightening, abducting-adducting, spinning in whole range of motion in shoulder joint; bending-straightening and rotation in all directions of joint in hand joint; bending-straightening, abducting-adducting, the inner rotation-external rotation of joint in Hip joint; bending- straightening in knee joint and bending- straightening in ankle joint. The way and how to do the exercises will be fully explained for the patient and his first-degree family in order to prevent any changes to the exercises to the extent possible. Patients are asked to carry out these exercises carefully and thoroughly until the end of the study and the investigator will directly supervise this during this study. After performing range of motion exercises for 4 weeks, the Barthel's daily activities questionnaire will be completed by the intervention group once again. Also, the quality of life questionnaire for burnt patients will be completed by patients three months after the intervention.

Category

Rehabilitation

2

Description

Control group: The Barthel's questionnaire and quality of life questionnaire were completed by patients one day prior to the intervention. Then patients in control group, went under routine hospital treatment and rehabilitation programs during 4 weeks. The questionnaire of daily life activities was completed again after one month. The quality of life questionnaire for burnt patients was completed three months after the beginning of intervention.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

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Sponsors / Funding sources

1

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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

Ahvaz 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**

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Web page address**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

Not applicable

Data Dictionary**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Undecided - It is not yet known if there will be a plan to make this available