Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Investigation of the effect of Occupation-Based Interventions on hand and upper extermity function in patients with hand burn injury

Protocol summary

Study aim
The Investigation of the effect of Occupation-Based Interventions on hand and upper extermity function in patients with hand burn injury

Design
Clinical practice with two intervention and control groups, parallel, double blind, and randomized groups

Settings and conduct
the Occupational Therapy Department of Shahid Motahari Hospital of Shahid Motahari Hospital is referenced. In the case of people with hand injury, those who have the conditions for entry into the study, sampling is done in accessible form.

Participants/Inclusion and exclusion criteria
Study criteria: 18 to 65 years old. 3 to 5 days after surgery. Having an acceptable level of cognitive performance, 21 or above, in the Mini Mental Status Examination test. Depth of burn 2 and 3 and burning area 2.5%. Not having any injuries such as fractures, tendon injuries, or injured infections. Psychological problems that cause non-cooperation with the implementation of therapeutic protocols. Exit criteria: Lack of cooperation and willingness to continue cooperation. Missing more than one meeting. Unwanted side effects after surgery such as infection, severe swelling and recurrence of ulcers.

Intervention groups
The control group received only usual rehabilitation interventions which included stretching, motor and sensory improvement exercises, splinting, exercises for increased endurance and muscle strength, management of scars and edema. The intervention group, in addition to receiving the usual interventions, receives acupuncture-based exercises, which are used in this group of CO-OP treatment protocols. Interventions in both intervention and control groups will begin one week after surg, and the duration of intervention per session and for both groups will be 45 minutes.

Main outcome variables
Canadian Occupational Performance Measure Michigan Hand Questionnaire Shortened Disabilities of the Arm, Shoulder and Hand Questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180908040970N1**
Registration date: **2020-01-19, 1398/10/29**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-19, 1398/10/29**
Update count: **0**

Registration date
2020-01-19, 1398/10/29

Registrant information

Name
Mahnoosh Khanipour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7711 2441

Email address
mah.pouroushan@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-02, 1398/08/11

Expected recruitment end date
2020-10-31, 1399/08/10

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Investigation of the effect of Occupation-Based Interventions on hand and upper extermity function in patients with hand burn injury

Public title

Occupation-Based Interventions

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

18-65 years old 3-5 days after surgery Having an acceptable level of cognitive performance, score 21 and above, in the Expedient Examination Test (MMSE). Depth of burn 2 and 3, and burn circumference 2.5%. Not having any injuries such as fractures, tendon injuries, or injured infections. Psychological problems that lead to non-cooperation with the implementation of therapeutic protocols

Exclusion criteria:

Lack of cooperation and willingness to continue cooperation. Missing more than two sessions. Unwanted side effects after surgery such as infection, severe swelling and recurrence of ulcers.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting and determining the number of samples, individuals are completely randomized using the random number table in two groups (standard protocol and standard protocol with CO-OP protocol).

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, none of the participants are aware of which intervention and control groups are involved, the assessor is not aware of how the exercises are carried out and the placement of people in each group at all stages of the study. The final analyst will not be aware of any interventions in each of the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran university of medical Sciences

Street address

school of rehabilitation science, madadkaran Lane, Shahid Shah Nazari Street, Mother Square, Mirdamad.

City

Tehran

Province

Tehran

Postal code

158754391

Approval date

2018-10-10, 1397/07/18

Ethics committee reference number

IR.IUMS.REC.1397.293

Health conditions studied

1

Description of health condition studied

Hand Burn Injury

ICD-10 code

T23.0

ICD-10 code description

Burn of unspecified degree of wrist and hand

Primary outcomes

1

Description

Occupational Performance rate in the Canadian Occupational Performance Measure

Timepoint

Time intervals for evaluation at the beginning of the study (before the intervention), after the second week, after the eighth week and after the sixteenth week.

Method of measurement

Canadian occupational Performance measure (COPM)

2

Description

Hand Performance rate in the Michigan Hand Questionnaire

Timepoint

Time intervals for evaluation at the beginning of the study (before the intervention), after the second week, after the eighth week and after the sixteenth week.

Method of measurement

Michigan Hand Questionnaire (MHQ)

3

Description
Disability rate in Shortened Disabilities of the Arm, Shoulder and Hand Questionnaire
Timepoint
Time intervals for evaluation at the beginning of the study (before the intervention), after the second week, after the eighth week and after the sixteenth week.
Method of measurement
Shortened Disabilities of the Arm, Shoulder and Hand Questionnaire(Q-DASH)

Secondary outcomes

1

Description
The amount of pain
Timepoint
Time intervals for evaluation at the beginning of the study (before the intervention), after the second week, after the eighth week and after the sixteenth week.
Method of measurement
Visual Analog Scale

2

Description
Goniometer
Timepoint
Time intervals for evaluation at the beginning of the study (before the intervention), after the second week, after the eighth week and after the sixteenth week.
Method of measurement
Goniometer

3

Description
Edema rate
Timepoint
Time intervals for evaluation at the beginning of the study (before the intervention), after the second week, after the eighth week and after the sixteenth week.
Method of measurement
meter

4

Description
Muscle strength
Timepoint
Time intervals for evaluation at the beginning of the study (before the intervention), after the second week, after the eighth week and after the sixteenth week.
Method of measurement
Dynamometer

5

Description
ability to perform Activities of Daily Living
Timepoint
Time intervals for evaluation at the beginning of the study (before the intervention), after the second week, after the eighth week and after the sixteenth week.
Method of measurement
Modified Barthel Index (MBI)

6

Description
Quality Of Life level
Timepoint
Time intervals for evaluation at the beginning of the study (before the intervention), after the second week, after the eighth week and after the sixteenth week.
Method of measurement
World Health Organization Quality Of Life-Brief (WHOQOL-BRIEF)

Intervention groups

1

Description
Intervention group: The intervention group received interventional interventions after two weeks (6 sessions) and received conventional interventions such as stretching, exercises for increasing passive and active motion, sensory improvement exercises, splinting, exercises for increasing tolerance and muscle strength, managing oscillation and edema; receiving interventions based on acupuncture The CO-OP protocol is used in this group.
Category
Rehabilitation

2

Description
Control group: The control group only received the most common rehabilitation interventions, including stretching, exercising of the passive and active motion amplification, sensory improvement exercises, splinting, exercises, increased tolerance and muscle strength, and management of scars and edema
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Motahhari Hospital
Full name of responsible person
Dr Lale Lajevardi
Street address
Rashid yasemi ave, zbove vanak sq, Valiyeasr ave
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Tehran
Province

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1996714353
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Kazem Malakouti
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Tehran
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1449614535
Phone
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Email
Mah.pouroushan@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Mahnoosh Khanipour
Position
Msc student
Latest degree
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Other areas of specialty/work
Occupational Therapy
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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
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
Yes - There is 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
Title and more details about the data/document
All of the data and information on the main and secondary outcomes of the post-print study are shared.
When the data will become available and for how long
The access period begins 6 months after the results are published.
To whom data/document is available
Learn to pronounce Data will be available only to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
1. Use data only to evaluate effective therapies. 2. Applicants must be legal entities registered in educational or scientific centers. 3. The applicant shall undertake not to use the data for personal gain or unrelated scientific studies and in other fields. 3. The requesting person shall undertake not to misuse data in unrelated contexts.
From where data/document is obtainable
The data can be accessed by contacting the following people and sending the requested information up to one week after receiving the request and confirming the conditions: 1.Mahnoosh Khanipour by Email Address: mah.pouroushan@gmail.com 2. Dr. Laleh Lajevardi by Email Address: laleh23275@yahoo.com 3. Dr. Ghorban Taghizadeh by Email Address: gh_taghizade@yahoo.com
What processes are involved for a request to access data/document
Access to the data can be done first via e-mail with the lead researcher studying the correspondence. Subsequently, the necessary information is sent by providing substantiated evidence of the eligibility requirements for the data and confirming the stated evidence and reasons. If the principal investigator fails to respond, the necessary guidance and counseling correspondence can be provided, which will be resubmitted in accordance with the above-mentioned conditions and steps.
Comments