

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the effectiveness of massage cupping on pain and quality of life in patient with trapezius myofascial syndrome

Protocol summary

Study aim

Evaluation of the effectiveness of massage cupping on pain, fatigue and quality of life in patient with trapezius myofascial syndrome

Design

This is a two arm parallel group randomized control clinical trial including intervention(A) and control(B) groups. The patients with trapezius myofascial syndrome assigned into one the two groups by using sealed envelopes. The patients, the persons which perform the intervention and the person who analyze the data are unaware about patient assignment.

Settings and conduct

40 patients with trapezius myofascial syndrome referred from physical medicine and rehabilitation office based on inclusion and exclusion criteria. After describing the study, method and the objectives, the patients signed an informed consent and divided in two group randomly by using sealed envelopes: 1-massage cupping therapy 2-control group. At first demographic and disease history questionnaire and SF-36 QOL questionnaire will be completed and pain will be measured using visual analog scale (VAS) for all patients then, the first group will be treated by massage cupping for 4 weeks(2 sessions a week), every session lasts 15 minutes. For the second group (control group), a routine exercise therapy was performed. The exercises consisted of three strengthening exercises and five stretching exercises for the upper, middle and lower trapezius muscles. Each movement was performed 10 repetitions and 3 times a day. All data will be collected after the last session of therapy as well as three months later. Data will be analyzed with SPSS using ANOVA and repeated measure test.

Participants/Inclusion and exclusion criteria

patient with trapezius myofascial syndrome

Intervention groups

Group A: massage cupping therapy and drug therapy
Group B: exercise therapy and drug therapy Drug

therapy: drug therapy for both groups: Tab
acetaminophen 500mg daily

Main outcome variables

Pain

General information

Reason for update

Correction of the control group

Acronym

IRCT registration information

IRCT registration number: **IRCT20180804040685N2**

Registration date: **2020-08-03, 1399/05/13**

Registration timing: **prospective**

Last update: **2021-05-03, 1400/02/13**

Update count: **2**

Registration date

2020-08-03, 1399/05/13

Registrant information

Name

Hamid Reza Fateh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2110

Email address

hr-fateh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

2020-08-07, 1399/05/17
Actual recruitment end date
 2021-01-11, 1399/10/22
Trial completion date
 2021-04-12, 1400/01/23

Scientific title
 Evaluation of the effectiveness of massage cupping on pain and quality of life in patient with trapezius myofascial syndrome

Public title
 Evaluation of the effectiveness of massage cupping in patient with trapezius myofascial syndrome

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 patient with trapezius myofascial syndrome according to physiatrist diagnosis 18-65 y/o VAS>2
Exclusion criteria:
 Patients with uncontrolled systemic disease Patients with similar symptoms such as radiculopathy, etc Patients with coagulopathy or treated with anticoagulants CNS disorders Mental disorders and bacterial infection Pregnant Local disease Participate in other studies and interventions Disinclination to continue participating in the present study

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

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **40**
 Actual sample size reached: **44**

Randomization (investigator's opinion)
 Randomized

Randomization description
 The patients primary evaluation, will be assigned into one of the 2 groups A or B randomly by using sealed envelopes, so that each patient picks up a sealed envelop in which the group A or B is defined and enters to one of the two 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

Ethic committee, Tehran University of Medical Sciences

Street address

Jalal aleahmad Highway

City

Tehran

Province

Tehran

Postal code

1417863181

Approval date

2019-06-03, 1398/03/13

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.177

Health conditions studied

1

Description of health condition studied

trapezius myofascial syndrome

ICD-10 code

ICD-10 code description

سندرم میوفاسیال

Primary outcomes

1

Description

pain

Timepoint

before and after intervention and three months after end of intervention

Method of measurement

Visual Analog Scale

2

Description

quality of life

Timepoint

before and after intervention and one and three months after end of intervention

Method of measurement

SF-36 QOL questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group(massage cupping): cupping will be perform by moving a cup over the trapezius muscle by imposing negative pressure trough suctioning.

Category

Rehabilitation

2

Description

Control group: control group receive routine exercise therapy and drug.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Saeed Reza Mehrpoor

Street address

Jalal Ale-ahmad highway

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hr-fateh@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Imam Khomeini Ave., Hasan Abad Sq., Sina Hospital
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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Hamid Reza Fateh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Hamidrezaq fateh

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

preservation of patients private limit

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

all data will be shared after making them non-identified-able the patients

When the data will become available and for how long

6 months after ending the study

To whom data/document is available

researchers in universities and scientific associations

Under which criteria data/document could be used

for confirming to be publication

From where data/document is obtainable

corresponding author

What processes are involved for a request to access data/document

email contact and accomplished legal process

Comments