

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 through 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

**City**

Tehran

**Province**

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**Postal code**

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**Phone**

+98 21 8822 5880

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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  
Tehran - Iran

**City**

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**Province**

Tehran

**Postal code**

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**Phone**

+98 21 6670 6142

**Email**

msahrai@tums.ac.ir

**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**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Hamidreza fateh

**Position**

Associate professor

**Latest degree**

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**Other areas of specialty/work**

Physical Medicine

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Postal code**

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**Phone**

+98 21 8822 5880

**Email**

hr-fateh@tums.ac.ir

**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 auther

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

email contact and accomplished legal process

**Comments**