

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation the efficacy of Pentoxifylline and placebo on Adhesive Capsulitis

#### Protocol summary

##### Study aim

The evaluation of Pentoxifylline efficacy on Adhesive Capsulitis

##### Design

Two arm parallel group double blind randomized controlled trial, single center.

##### Settings and conduct

the study is double blind( both patient and clinician) and is performed in rheumatologic clinic. blindness is done by a third person who is pharmacist with computerized randomization.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of adhesive capsulitis is made by a Rheumatologist; informed consent is obtained;  
Non Inclusion criteria: patient dissatisfaction; adhesive capsulitis due to malignancy; history of cardiac arrhythmia; history of NSAID use; pregnancy or lactation

##### Intervention groups

Intervention group: prescription of pentoxifylline, BID, for 3 months. Control group: prescription of placebo, BID, for 3 months.

##### Main outcome variables

affected shoulder range of motion; serum TNF-alpha level

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181103041531N1**

Registration date: **2019-02-28, 1397/12/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-02-28, 1397/12/09**

Update count: **0**

##### Registration date

2019-02-28, 1397/12/09

#### Registrant information

##### Name

Leila Mahmoudieh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2360 2188

##### Email address

l.mahmoudieh@sbmu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2019-01-21, 1397/11/01

##### Expected recruitment end date

2020-04-19, 1399/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

2022-01-21, 1400/11/01

#### Scientific title

Evaluation the efficacy of Pentoxifylline and placebo on Adhesive Capsulitis

#### Public title

The evaluation of Pentoxifylline efficacy on Adhesive Capsulitis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

diagnosis of adhesive capsulitis is made by a Rheumatologist informed consent is obtained

##### Exclusion criteria:

patient dissatisfaction adhesive capsulitis secondary to malignancy history of cardiac arrhythmia history of NSAID

use pregnancy or lactation

## Age

From **18 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

## Sample size

Target sample size: **72**

Actual sample size reached: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Those patients who are diagnosed as adhesive capsulitis by rheumatologist are randomly assigned to case or control groups. Randomization will be done using random number table.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

randomization is done by a third person and participants and doctor are both blind.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti university of medical science

##### Street address

Labbafinejad Hospital, 9th Boostan, Pasdaran ave.

##### City

Tehran

##### Province

Tehran

##### Postal code

1666663111

#### Approval date

2017-10-28, 1396/08/06

#### Ethics committee reference number

IR.SBMU.MSP.REC.1396.515

## Health conditions studied

### 1

#### Description of health condition studied

Adhesive capsulitis

#### ICD-10 code

M75.0

#### ICD-10 code description

Adhesive capsulitis of shoulder

## Primary outcomes

### 1

#### Description

affected shoulder range of motion

#### Timepoint

before intervention and after intervention, weekly up to 3 months

#### Method of measurement

physical examination

### 2

#### Description

level of TNF-alpha in blood

#### Timepoint

before intervention and at the end of study

#### Method of measurement

blood measurement

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In this group pentoxifylline, oral tablet 400mg which is produced by Amin pharmaceutical company is prescribed twice daily for 3 months

#### Category

Treatment - Drugs

### 2

#### Description

Control group: In this group placebo, oral tablet 400mg, which is produced by Amin pharmaceutical company is prescribed twice daily for 3 months

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Labbafinejad hospital  
**Full name of responsible person**  
Leila Mahmoudieh  
**Street address**  
9th Bosstan, Pasdaran street  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1666663111  
**Phone**  
+98 21 2360 2188  
**Email**  
l.mahmoudieh@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Dr. Afshin Zargh  
**Street address**  
Next to Taleghani hospital, Shahid Arabi ave., Yaman street, Chamran boulevard  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1985717443  
**Phone**  
+98 21 2243 9780  
**Email**  
Mpajouhesh@sbmu.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shahid Beheshti 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**  
Shahid Beheshti University of Medical Sciences

**Full name of responsible person**  
Dr. Leila Mahmoudieh  
**Position**  
assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Internal Medicine  
**Street address**  
Labbafinejad hospital, 9th Boostan, Pasdaran ave.  
**City**  
Tehran  
**Province**  
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**Postal code**  
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**Email**  
l.mahmoudieh@sbmu.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Dr. Leila Mahmoudieh  
**Position**  
Assistant professor  
**Latest degree**  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Dr. Leila Mahmoudieh  
**Position**  
assistant professor  
**Latest degree**  
Specialist  
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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**

there is no plan to share data with other researches or organizations yet

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

all collected data will be deidentified before sharing.

**When the data will become available and for how long**

data will be available 6 months after publication.

**To whom data/document is available**

Data is available for academic people and organizations.

**Under which criteria data/document could be used**

there is no limitation on how to use data

**From where data/document is obtainable**

l.mahmoudieh@sbmu.ac.ir

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

Request should be sent by email and after identity obtaining, data will be sent by email

**Comments**