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 bind(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 contest is obtained; Non Inclusion criteria: patient dissatisfaction; adhesive capsulitis due to malignancy; history of cardiac arhythmia; 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 contest is obtained
Exclusion criteria:
patient dissatisfaction adhesive capsulitis secondary to malignancy history of cardiac arhythmia 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
Tehran

Postal code
1666663111

Phone
+98 21 2360 2188

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

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+98 21 2360 2188

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l.mahmoudieh@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Leila Mahmoudieh

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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 identitiy obtaining, data will be sent by email

Comments