

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### The effects of platelet lysate therapy on cuff tendinopathy

#### Protocol summary

##### Study aim

Effect of platelet lysate on cuff tendinopathy

##### Design

This study is not-blind, phase 3 clinical trials on 40 patients based on inclusion and exclusion criteria, the study procedure will be explained to patients, and informed consent will be obtained before the study and classified into two groups of PL and control group without any treatment.

##### Settings and conduct

The following items for the patients who are most relevant, recorded: 1) Pain by visual analog scale (VAS) 2) Cuff function by the Shoulder Pain and Disability Index (SPADI) 3) Cuff motion range by jointometry. After PL and quality control, patients will be referred to the Rehabilitation and Physical Medicine Department of the Shahid Madani Hospital for the injection of PL in the cuff. A second injection is repeated at intervals of 21 days. Then, in order to evaluate the effect of PL on patients in the intervals of 1 and 3 months after the first injection, the cases mentioned above will be recorded.

##### Participants/Inclusion and exclusion criteria

A total of 40 Men and women between the ages of 18 and 75 with cuff tendinopathy and exclusion criteria Pregnant women or women who are breastfeeding, People with malignancy, hemorrhagic diseases, history of anemia, History of cuff surgery in the last 3 months

##### Intervention groups

Platelet lysate (PL) treatment group , which will be injected 2 cc of PL in the shoulder tendon area and its effectiveness will be assessed in 1 to 3 months after the first injection. In control group without any treatment, patients' condition will be assessed in 1 and 3 months after the beginning of the study

##### Main outcome variables

1- Determining cuff pain by VAS in all phases of clinical trial 2- Determination of cuff function by Shoulder Pain and Disability Index (SPADI) in all phases of clinical trial 3- Determine the range of cuff motion by manual jointometry in all phases of the trial

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160422027520N17**

Registration date: **2020-04-14, 1399/01/26**

Registration timing: **prospective**

Last update: **2020-04-14, 1399/01/26**

Update count: **0**

##### Registration date

2020-04-14, 1399/01/26

##### Registrant information

##### Name

Mehdi Yousefi

##### Name of organization / entity

Department of Immunology, Faculty of Medicine,  
Tabriz University of Medical Sciences, Tabriz, Iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3336 4665

##### Email address

yousefime@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-19, 1399/02/30

##### Expected recruitment end date

2020-08-20, 1399/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

The effects of platelet lysate therapy on cuff tendinopathy

**Public title**

Treatment of cuff tendinopathy with platelet lysis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Men and women between the ages of 18 and 75 with cuff tendinopathy The availability of individual during the study period

**Exclusion criteria:**

People under the age of 18 and over 75 years Pregnant women or women who are breastfeeding People with malignancy, People with severe heart disease, uncontrolled diabetes mellitus, hemorrhagic diseases, history of anemia, arthritis, fibromyalgia and chronic fatigue syndrome Those linked to acetaminophen or Vicodin or a history of drug misuse History of cortisone injections in the last 6 weeks The use of non-steroidal anti-inflammatory drugs 1 week ago Having hemoglobin less than 11 g / dl and platelet count less than 150000 / μ. The use of inhibitors of platelet aggregation and anti-coagulation such as heparin History of cuff surgery in the last 3 months

**Age**

From **18 years** old to **75 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****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**

Ethics committee of Tabriz University of Medical Sciences

**Street address**

Tabriz University of Medical Sciences , Daneshghah st, Tabriz,

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Approval date**

2020-01-20, 1398/10/30

**Ethics committee reference number**

IR.TBZMED.REC.1398.1133

**Health conditions studied****1****Description of health condition studied**

Cuff tendinopathy

**ICD-10 code**

M75.101

**ICD-10 code description**

Unspecified rotator cuff tear or rupture of right shoulder, not specified as traumatic

**Primary outcomes****1****Description**

Determining cuff pain by VAS in all phases of clinical trial

**Timepoint**

1 and 3 months after the first injection

**Method of measurement**

Questionnaire (VAS)

**2****Description**

Determination of cuff function by Shoulder Pain and Disability Index (SPADI) in all phases of clinical trial

**Timepoint**

1 and 3 months after the first injection

**Method of measurement**

Questionnaire (SPADI)

**3****Description**

Determine the range of cuff motion by manual jointometry in all phases of clinical trial

**Timepoint**

1 and 3 months after the first injection

**Method of measurement**

Range of motion (Degree)

**Secondary outcomes**

empty

## Intervention groups

1

### Description

Intervention group: In this group of patients, 10 ml of blood will be taken by PRP-specific syringe manufactured by Noavaran Salamat Arjang CO. and according to kit protocol, we will separate the PRP and then produce Platelet lysate. The Platelet lysate will then be injected by a physician into the cuff tendon of the patient with cuff tendinopathy. The Platelet lysate injection volume will be 2 cc. The injection will be repeated with a 21 days apart.

### Category

Treatment - Drugs

2

### Description

Control group: No drugs will be injected into patients in this group

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Shahid Madani Hospital, Tabriz

#### Full name of responsible person

Mehdi Yousefi, Ph.D Of Medical Immunology

#### Street address

Shahid Madani Hospital, Golbad Avenue, Tabriz

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166614766

#### Phone

+98 41 3335 7767

#### Email

mehdi\_yusefi@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Ata Mahmoodpoor

#### Street address

Tabriz University of Medical Sciences

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166614766

#### Phone

+98 41 3336 4667

#### Email

amahmoodpoor@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

#### Full name of responsible person

Mehdi Yousefi

#### Position

PhD of Immunology

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Immunology

#### Street address

Department of Immunology, Tabriz University of Medical Sciences,

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166614766

#### Phone

+98 41 1336 4665

#### Fax

#### Email

yousefime@tbzmed.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Mehdi Yousefi

**Position**

PhD of Immunology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Immunology

**Street address**

Department of Immunology, Tabriz University of Medical Sciences,

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 41 1336 4665

**Fax****Email**

yousefime@tbzmed.ac.ir

**Web page address**

Medical Sciences,

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 41 1336 4665

**Fax****Email**

yousefime@tbzmed.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mehdi Yousefi

**Position**

PhD of Immunology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Immunology

**Street address**

Department of Immunology, Tabriz University of

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be 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