

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 joiniometry. 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 joiniometry 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 / mm³ The use of inhibitors of platelet aggregation and anticoagulation 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 , Daneshgah 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**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

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