

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of the Effectiveness of Platelet-Rich Plasma (PRP) Therapy with Steroid Therapy in Improving the Clinical Symptoms of Patients with Rheumatoid Arthritis.

Protocol summary

Study aim

Evaluation of the efficacy of Platelet-Rich Plasma (PRP) therapy in Rheumatoid arthritis Patients.

Design

A clinical trial with a control group, parallel-group randomized trial with blinded outcome assessment, phase 3 on 40 patients.

Settings and conduct

The study will be conducted at the Autoimmune Diseases Research Center of Shiraz University of Medical Sciences. Drug prescription and therapeutic intervention will be done in the rheumatology department of Hafez Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with rheumatoid arthritis.
Exclusion criteria: patients who are being treated or suffering from other autoimmune diseases.

Intervention groups

The control group is Rheumatoid arthritis patients treated with standard steroid medicine. The experimental group is Rheumatoid arthritis Patients who are treated with platelet-rich plasma.

Main outcome variables

1. Determination of Erythrocyte Sedimentation Rate, C-Reactive Protein, Anti Citrullinated peptide Antibody, Antinuclear Antibodies, and Rheumatoid Factor serum levels in patients before and after Platelet-Rich Plasma therapy. 2. Evaluation of Interleukin 1 beta synovial fluid levels in patients before and after Platelet-Rich Plasma therapy. 3. Evaluation of radiological examination in Rheumatoid Arthritis patients before and after Platelet-Rich Plasma therapy. 4. Evaluation of synovial fluid cell counts in Rheumatoid Arthritis patients before and after Platelet-Rich Plasma therapy. 5. Calculation of Disease Activity Score-28 in Rheumatoid Arthritis patients before and after Platelet-Rich Plasma therapy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221203056694N1**

Registration date: **2023-01-28, 1401/11/08**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-28, 1401/11/08**

Update count: **0**

Registration date

2023-01-28, 1401/11/08

Registrant information

Name

Nasser Gholijani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-06-21, 1402/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Platelet-Rich Plasma (PRP) Therapy with Steroid Therapy in Improving the Clinical Symptoms of Patients with Rheumatoid Arthritis.

Public title

Effect of platelet-rich plasma therapy in rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

This study will be done on 40 patients with RA diseases who were diagnosed at the rheumatology clinic of Hafez Hospital, according to the American College of Rheumatology/European League Against Rheumatism criteria.

Exclusion criteria:**Age**

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization methods: The method of simple random assignment is that odd numbers are given to the intervention group (platelet-rich plasma prescription) and even numbers are given to the control group (common treatment with triamcinolone prescription). Then, according to the number of the studied sample, the relevant numbers are extracted from the table of random numbers or using a computer, each number is written on a card and placed in an envelope, and the envelopes are sealed, and the patient's number is written on each envelope. And the first patient who is registered in the study and enters the study will be given the envelope related to patient number 1, patient number 2 will be given envelope number 2 and so on, this work will continue until the end of the study sample. The person who prepares the envelopes will be different from the person who registers the patients and provides the envelopes to the patients. Considering that the treatment allocation of patients is done by the doctor, in order to prevent the influence of the doctor's opinion, the registration of the patients and their allocation in each of the groups will be done by the doctor's assistant and someone other than the doctor.

Blinding (investigator's opinion)

Double blinded

Blinding description

In our study, the investigator, the physician evaluating

the treatment, those responsible for data collection, and those evaluating the outcome are blinded. In this study, in order to avoid applying the personal opinion of the doctor evaluating the course of treatment, he/she will be unaware of the type of treatment received in each of the research subjects, and it is important to note that during the stages of the research, due to the patient's contact with the doctor, blinding will not disappear. Those responsible for data collection should be unaware of the type of treatment received by the people participating in the research. Those who evaluate the results are chosen outside the treatment team so that even if the researcher knows the type of intervention assigned to the participants in the research, their knowledge does not affect the data analysis.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

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Shiraz University of Medical Sciences, Zand St., Shiraz, Iran

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71348-14336

Approval date

2019-06-25, 1398/04/04

Ethics committee reference number

IR.SUMS.REC.1398.596

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

Rheumatoid arthritis (RA)

ICD-10 code

M06

ICD-10 code description

Other rheumatoid arthritis

Primary outcomes

1

Description

Erythrocyte Sedimentation Rate (ESR)

Timepoint

Before and after Platelet-rich plasma (PRP) therapy

Method of measurement

Westergren method

2

Description

C-reactive protein (CRP)

Timepoint

Before and after Platelet-rich plasma (PRP) therapy

Method of measurement

ELISA

3

Description

Anti Citrullinated peptide Antibody

Timepoint

Before and after Platelet-rich plasma (PRP) therapy

Method of measurement

ELISA

4

Description

Antinuclear Antibody (ANA)

Timepoint

Before and after Platelet-rich plasma (PRP) therapy

Method of measurement

ELISA

5

Description

Rheumatoid Arthritis (RA) factor

Timepoint

Before and after Platelet-rich plasma (PRP) therapy

Method of measurement

ELISA

6

Description

Interleukin-1 beta

Timepoint

Before and after Platelet-rich plasma (PRP) therapy

Method of measurement

ELISA

7

Description

Radiological Examination

Timepoint

Before and after Platelet-rich plasma (PRP) therapy

Method of measurement

Radiology

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Platelet-rich plasma (PRP) therapy uses injections of a concentration of a patient's own platelets to accelerate the healing of injured tendons, ligaments, and joints. To prepare 4-5 cc PRP, 30-40 cc venous blood samples from the antecubital vein will be collected in a sterile acid citrate dextrose tube using an 18G needle to avoid traumatizing platelets. Then, the blood with anticoagulant will be centrifuged twice: First, we will centrifuge the blood at 1,800 rpm for 15 minutes to separate erythrocytes and Transfer the supernatant plasma containing platelets into another sterile tube (without anticoagulant). Then the tube will be centrifuged at 3,500 rpm for 5 minutes to concentrate platelets. The lower 1/3rd is PRP and the upper 2/3rd is platelet-poor plasma (PPP). PPP will be removed and platelet pellets will be suspended in a minimum quantity of plasma (2-4 mL) by gently shaking the tube. The final product is 4-5 cc of PRP-containing leukocytes. Approximately 0.5 cc PRP will be collected for platelet counting. Finally, 0.0425 mL of 10% calcium chloride per 1 mL of PRP will be added to the final product to activate the platelets. PRP in a sterile condition will be injected by a physician using a classic lateral approach with a 22 G needle with the subjects in a supine position with the knee in full extension. The second injection will be administered under the same conditions as the first injection., three months later. During the follow-up period, the patients will be asked to take acetaminophen only when necessary, or acetaminophen with codeine for persistent pain. The patients will be instructed not to take drugs in the 48 hours before an assessment. Patients will be prohibited from using other analgesics, NSAIDs, steroids, or medications which might have influenced platelet count or function. Exercise or physical treatment will not be allowed during the study period to eliminate synergistic effects. Patients will be evaluated before the treatment and the 3 months after the treatment with a clinical laboratory exam and radiological examination. A radiological examination of the knee is performed before and at the end of the study.

Category

Treatment - Other

2

Description

Control group: Prescribing conventional steroid drugs in the treatment of rheumatoid arthritis. Patients in this group will take intra-articular injections of triamcinolone, 80 mg, at the beginning of the study and three months later. Frequency of patients' evaluations: History taking, physical examination {including assessment of VAS (visual analog scale 0-10) for joint pain at rest (VASR),

VAS for joint pain at motion (VASM), and VAS for joint swelling (VASSw) at baseline, and months three. Blood sampling will be performed at baseline and in months three. Inflammatory cytokines will be checked at baseline and at the end of the study. Synovial fluid sampling will be performed at each time intra-articular injection. Radiographs will be taken at the baseline and the end of the study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Hospital, Rheumatology Department

Full name of responsible person

Mohammad Ali Nazarinia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Shiraz University of Medical Sciences

Full name of responsible person

Nasser Gholijani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Other areas of specialty/work

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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

The participants' data is part of their privacy.

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

No - There is not 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