

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The comparison of treatment success rate of arthroscopic arthrocentesis by injection of PRP versus hyaluronic acid (single or combinative) for patients with TMJ osteoarthritis.

Protocol summary

Study aim

The comparison of treatment success rate of arthroscopic arthrocentesis by injection of PRP versus hyaluronic acid (single or combinative) for patients with TMJ osteoarthritis.

Design

The randomized double-blinded clinical trial without the placebo. Patients and the assessor of the outcome would be blind to the study. The assessor would be another surgeon who is blind to the study.

Settings and conduct

Mashhad dental school, oral and maxillofacial department

Participants/Inclusion and exclusion criteria

All of the patients with TMJ osteoarthritis (in one or both joints) with age range 15-60 years old who received conservative treatment; patients with ASA 1 or 2 status; patients without allergy to HA and PRP; patients without history of cardiovascular or Coagulation problems; Patients without any TMJ surgery; patients without a history of neurological, immunologic head & neck and TMJ malignancy; patients Without history of problem in connective tissue such as rheumatoid arthritis

Intervention groups

Arthroscopic arthrocentesis will be performed in 3 interventional groups. Intervention group 1: Intra-articular injection of hyaluronic acid. Intervention group 2: Intra-articular injection of PRP (Platelet rich plasma). Intervention group 3: Intra-articular injection of combination hyaluronic acid and PRP. No control group is available in this study.

Main outcome variables

Joint sounds, Joint pain, Maximum Mouth Opening (MMO), protrusive and lateral movement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150613022697N6**

Registration date: **2018-11-22, 1397/09/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-22, 1397/09/01**

Update count: **0**

Registration date

2018-11-22, 1397/09/01

Registrant information

Name

Sahand Samiee rad

Name of organization / entity

mashhad dental school,oral and maxillofacial department

Country

Iran (Islamic Republic of)

Phone

+98 51 3883 7289

Email address

samieerads@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-12, 1397/07/20

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of treatment success rate of arthroscopic arthrocentesis by injection of PRP versus hyaluronic acid (single or combinative) for patients with TMJ osteoarthritis.

Public title

The comparison of treatment success rate of injection of hyaluronic acid versus PRP for patients with TMJ osteoarthritis.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All of the patients with TMJ osteoarthritis (in one or both joints) with age range 15-60 years old who received conservative treatment. Patients with ASA 1 or 2 status Patients with normal cardiovascular or coagulation system

Exclusion criteria:

Patients with previous TMJ surgery Patients with the history of neurological, immunologic head & neck and TMJ malignancy Patients with the history of problem in connective tissue such as rheumatoid arthritis Patients with the history of NSAIDS usage. Patients with the allergy to HA and PRP

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization using the table of random numbers would be used. Allocation concealment of random codes would be carried out.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and the assessor the outcome would be blind to the study. The assessor would be another surgeon who is blind to the study.

Placebo

Not used

Assignment

Parallel

Other design features

The randomized double-blinded clinical trial without the placebo

Secondary Ids

empty

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

Ethics committee of Mashhad university of medical sciences

Street address

Ghoreishi building, Daneshghah avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2018-09-12, 1397/06/21

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1397.058

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

Temporomandibular joint osteoarthritis

ICD-10 code

M26.6

ICD-10 code description

Temporomandibular joint disorders

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

Maximum Mouth Opening (MMO) rate

Timepoint

One day before, 1, 3, 6 and 12 months after arthrocentesis

Method of measurement

Ruler in millimeters

2**Description**

Jaw protrusive movement rate

Timepoint

One day before, 1, 3, 6 and 12 months after arthrocentesis

Method of measurement

Ruler in millimeters

3**Description**

jaw lateral Movement rate

Timepoint

One day before, 1, 3, 6 and 12 months after arthrocentesis

Method of measurement

Ruler in millimeters

4**Description**

Joint sounds presence

Timepoint

One day before, 1, 3, 6 and 12 months after arthrocentesis

Method of measurement

Yes / No

5**Description**

Joint pain amount

Timepoint

One day before, 1, 3, 6 and 12 months after arthrocentesis

Method of measurement

VAS scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: arthroscopic arthrocentesis with intra-articular injection of 1cc hyaluronic acid

Category

Treatment - Surgery

2**Description**

Intervention group: arthroscopic arthrocentesis with intra-articular injection of 1cc PRP (Platelet rich plasma).

Category

Treatment - Surgery

3**Description**

Intervention group: arthroscopic arthrocentesis with intra-articular injection of 1cc Hyaluronic acid combination with PRP

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center**

Name of recruitment center

Ghaem hospital

Full name of responsible person

Sahand samiee rad

Street address

Mashhad dental school, Vakil abad street.

City

Mashhad

Province

Razavi Khorasan

Postal code

9176813111

Phone

+98 51 3882 9501

Fax

+98 51 3882 9500

Email

samieerads@mums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Saeed Eslami

Street address

Ghoreishi building, Daneshgah avenue.

City

mashhad

Province

Razavi Khorasan

Postal code

91779448959

Phone

+98 51 3841 2081

Fax

+98 51 3841 2081

Email

eslamis@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

30

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

Mashhad University of Medical Sciences

Full name of responsible person

Sahand Samiee rad

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

oral and maxillofacial surgery department, Mashhad dental school, Vakil abad street.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3882 9501

Fax

+98 51 3882 9500

Email

samieerads@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Sahand Samiee rad

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

oral and maxillofacial surgery department, Mashhad dental school, Vakil abad street.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3882 9501

Fax

+98 51 3882 9500

Email

samieerads@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Negin Vatanparast

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

oral and maxillofacial surgery department, Mashhad dental school, Vakil abad street.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3843 1448

Fax

+98 51 3882 9500

Email

Negin.vatanparast@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected unindetified data would be shared for all researchers.

When the data will become available and for how long

The access to data will be started 6 months after publication.

To whom data/document is available

The data would only be available for people working in academic institutions.

Under which criteria data/document could be used

It is allowed to use the data for meta-analysis and systematic reviews.

From where data/document is obtainable

The data can be obtained via email, from the corresponding researches (Dr Sahand samiee rad). E-mail: samieerads@mums.ac.ir

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

The new research proposal and the processes details

should be e-mailed to corresponding researcher in order to get the access permission.

Comments