

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation of effect of PRP on temporomandibular disorder(TMD)

Protocol summary

Study aim

Evaluation of PRP (platelet rich plasma)effect on Temporomandibular disorders(TMD)

Design

Two arm parallel group randomised trial

Settings and conduct

All the patients referring to maxillofacial surgery department of Azad Dental School and Bouali Hospital with:pain,limitation in movement,goint sounds,deviation of mandible in mouth opening

Participants/Inclusion and exclusion criteria

nclusion criteria:PainLimitation in movement,Joint sounds,Deviation of mandible in mouth opening Exlusion criteria:Systemic deases,Patients candidated for temporomandibular joint(TMJ) surgery,Disk displacement without reduction

Intervention groups

PRP injection in one side(TMJ) and the other side as witness

Main outcome variables

Decrease in pain,Limitation in movement,Joint sounds,Deviation of mandible in mouth opening of patients despite effectivness of PRP injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180503039510N1**

Registration date: **2018-05-29, 1397/03/08**

Registratation timing: **registered_while_recruiting**

Last update: **2018-05-29, 1397/03/08**

Update count: **0**

Registration date

2018-05-29, 1397/03/08

Registrant information

Name

Mehdi Sezavar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3331 1107

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-01-01, 1395/10/12

Expected recruitment end date

2018-08-01, 1397/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of PRP on temporomandibular disorder(TMD)

Public title

Evaluation of effect of PRP on TMD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pain Limitation in movement Joint sounds Deviation of mandible in mouth opening

Exclusion criteria:

Systemic deases Patient candidate for tmj surgery Disk displacement without reduction

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 20

More than 1 sample in each individual

Number of samples in each individual: 2

Right and left temporomandibular joint(TMJ)

Randomization (investigator's opinion)

Not randomized

Randomization description

Choosing one tmj as witness and the other one as case

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 Azad Dental School

Street address

No.5 ,9 th Neyestan Alley, Pasdaran Ave

City

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Province

Tehran

Postal code

1913633151

Approval date

2016-05-15, 1395/02/26

Ethics committee reference number

IR.IAU.DENTAL.REC.1395,50

Health conditions studied

1

Description of health condition studied

Temporomandibular disorder(TMD)

ICD-10 code

M26.6

ICD-10 code description

Temporomandibular joint disorders

Primary outcomes

1

Description

Temporomandibular jointPain

Timepoint

At the begining of study and 2,4 and 6 month later

Method of measurement

Visual Analogue Scale questionarie

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: PRP injection in temporomandibular joint of one side in included patients(20 patients are being studie)6CC of patients blood will be transfused into sterile tubes coated with anti coagulant made by CHOUKRON company and centrifuged for3 minutes with1600 r/min,after formation of 3 layers in the tube ,the middle layer including platelet rich plasma or PRP is extracted,then a line is drwn joining the tragus to the lateral canthus(in the side to be injected),0.6 ml is injected in the point 10mm anterior to tragus (in the drawn line) and 2mm below,soft diet until one week is suggested to patient . index including pain,mouth opening,joint souds and jaw deviation in opening will be registered just at the time of injection and 2,4 and 6 months later and documented in related forms.

Category

Treatment - Other

2

Description

Control group: The temporomandibular joint in the side which has not been injected PRP,whitout any additional procedure, is considered as control group,and the indexes pain, limitation in joint movement,joint sound and deviation of mandible in opening at the begining of study and 2,4 and six months later the as intervention side is registered and finally compared with intervention group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Maxillofacial department of Bouali Hospital

Full name of responsible person

Mehdi Sezavar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
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
Islamic Azad University
Proportion provided by this source
1
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
Islamic Azad University
Full name of responsible person
Mehdi Sezavar
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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