

Injection into the temporomandibular joint by the traditional way and the guided way

Submission date 22/06/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/07/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/07/2024	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Today, guided procedures are popular because they increase the predictability and the safety of the treatment provided to patients. Guidance with ultrasound imaging is a safe procedure without any side effects. This study aims to obtain more accurate injections and follow up the results after the injections, and investigate the role of the guidance in reducing the symptoms associated with temporomandibular joint disorders (a condition affecting the movement of the jaw).

Who can participate?

Patients aged 18-60 years with temporomandibular joint disorders

What does the study involve?

Platelet-rich plasma (PRP) was injected with a contrast medium and the mixture was delivered into the upper joint space through reference points drawn on the face (non-guided method) in 12 patients, while the mixture was delivered into the upper joint space in the remaining 12 patients using ultrasound guidance followed by a CBCT scan to determine the location of the mixture in the tissues, and then the patients were followed up several times for 3 months after the injection. The following were measured: the duration of the session, the number of re-injections, and the number of redirections. Pain at rest and function were also recorded in the first 3 days after the injection, and the maximum mouth opening, joint sounds, and pain when palpating the joint were followed up 1 week, 1 month and 3 months after the injection.

What are the possible benefits and risks of participating?

The study does not involve any risks as the PRP is taken from the patient and the contrast media is tested before it is delivered to the joint tissues.

Where is the study run from?

Damascus University (Syria)

When is the study starting and how long is it expected to run for?

August 2021 to April 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
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Contact information

Type(s)

Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

A randomized clinical study of the accuracy of intra-temporomandibular joint injections combining non-guided injection with ultrasound-guided injection, with a comparison of the procedure and therapeutic efficacy

Study objectives

Does ultrasound guidance help to obtain more accurate, easier, and more efficient injections in treating symptoms associated with temporomandibular joint disorders compared to the non-guided method?

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 30/08/2021, Damascus University (Damascus, Damascus, -, Syria; +963 (0)1133923192; ap.srd@damascusuniversity.edu.sy), ref: 231-290424-DN

Study design

Randomized controlled clinical study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Dental clinic

Study type(s)

Treatment, Efficacy

Participant information sheet

Not available in web format

Health condition(s) or problem(s) studied

Temporomandibular joint disorders

Interventions

Participants were randomly allocated by drawing cards to non-guided injection or ultrasound-guided injection.

Platelet-rich plasma (PRP) was injected with contrast medium Ominpque 350 mg and the mixture was delivered to the joint through reference to points drawn on the face in 12 patients.

While the mixture was delivered to the remaining 12 patients using ultrasound guidance, this was followed by a CBCT scan to determine the location of the mixture in the tissues, and then the patients were followed up several times for 3 months after the injection.

Intervention Type

Procedure/Surgery

Primary outcome measure

1. Accuracy of the injected mixture location measured using CBCT imaging just after the mixture is delivered
2. Maximum mouth opening measured in millimeters at baseline, after 1 week, 1 month, and 3 months
3. Pain caused by tissue penetration measured using visual analogue score (VAS) at rest mandibular position 12, 24 and 48 hours after injection
4. Pain when chewing measured using VAS at 12, 24 and 48 hours after injection
5. Pain on TMJ palpation measured using VAS before injection and after 1 week, 1 and 3 months
6. Presence of joint sounds measured using auscultation and palpation before injection, after 1 week, 1 and 3 months

Secondary outcome measures

Optimal PRP and iodinated contrast agent mixture ratio for TMJ CBCT arthrography, determined using CBCT imaging and questionnaire (this part of the study was done before the main part that involved 24 samples, aiming to find the appropriate mixture for use in the primary objectives of the study)

Overall study start date

30/08/2021

Completion date

30/04/2024

Eligibility

Key inclusion criteria

1. Patients who complain of at least one of the following: joint pain, joint pain, or decreased mouth opening
2. Healthy patients who do not have general diseases that affect healing
3. Patients who have not had their temporomandibular joint treated surgically
4. Aged 18-60 years
5. There is no infection at the injection site
6. Insensitivity to the components of the injection
7. There are no kidney diseases affecting the indication for contrast media

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

60 Years

Sex

Both

Target number of participants

24

Total final enrolment

24

Key exclusion criteria

1. Injection site infection during follow-up periods
2. Patients receiving long-term dental treatment or whose joint area was affected by unusual trauma during the follow-up period
3. Patient's non-compliance with follow-ups
4. The presence of advanced joint problems that require surgical treatment, category IV and V, according to Dimitroulis G (2013)

Date of first enrolment

30/01/2023

Date of final enrolment

30/01/2024

Locations

Countries of recruitment

Syria

Study participating centre

Damascus University

Faculty of Dentistry

Almazzeh

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Sponsor information

Organisation

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Sponsor details

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Sponsor type

University/education

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Funder(s)**Funder type**

University/education

Funder Name

Damascus University

Alternative Name(s)

University of Damascus, , DU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Syria

Results and Publications**Publication and dissemination plan**

Planned publication in a peer-reviewed journal

Intention to publish date

01/07/2024

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date