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

Submission date
22/06/2024

Recruitment status
No longer recruiting

Registration date
16/07/2024

Overall study status
Completed

Last Edited
16/07/2024

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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Public, Scientific, Principal investigator

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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@damascusuniverity.edu.sy), ref: 231-290424-DN

Primary study design
Interventional

Study design
Randomized controlled clinical study

Study type(s)
Treatment, Efficacy

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(s)
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

Key secondary outcome(s)
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

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
Damascus
Syria
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Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

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

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