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Comparing injecting botulinum toxin type A in the masseter muscle only to the additional injection in the lateral pterygoid muscle in patients with bruxism

Submission date 20/12/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 20/12/2024	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/12/2024	**Condition category** Oral Health	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Bruxism is when you clench, grind or gnash your teeth. Botulinum toxin type A (BTX/A) injections in patients with bruxism decrease the muscle activity of the injected muscles, alleviate pain, and reduce the severity of bruxism. Most studies have focused on injections into the masseter and temporalis muscles at different doses, as these muscles are among the levator muscles of the mandible (lower jaw). This study aims to compare the treatment outcomes of BTX/A injections into the masseter and lateral pterygoid muscles with injections into the masseter muscle only in patients with bruxism.

Who can participate?
Patients aged 18-40 years with bruxism

What does the study involve?
Patients are randomly divided into two groups:
Group 1: BTX/A injections in the masseter and lateral pterygoid muscles
Group 2: BTX/A injections in the masseter muscle only

What are the possible benefits and risks of participating?
Benefits: Participants will receive treatment for bruxism.
Risks: There is a risk of a painful injection.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
April 2021 to November 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Mawia Karkoutly, mawia95.karkoutly@damascusuniversity.edu.sy, mawiamaherkarkoutly@hotmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Mawia Karkoutly

ORCID ID
https://orcid.org/0000-0003-0227-1560

Contact details
Mazzeh
Damascus
Syria
Nill
+963 (0)992 647 528
mawia95.karkoutly@damascusuniversity.edu.sy

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Comparative effectiveness of injecting botulinum toxin type A in the masseter muscle only to the additional injection in the lateral pterygoid muscle in patients with bruxism: a randomized controlled trial

Study objectives
The null hypothesis is that BTX/A injections into the masseter and lateral pterygoid muscles in patients with bruxism would not improve the treatment outcomes when only injected into the masseter muscle.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/04/2021, The Biomedical Research Ethics Committee (Mazzeh, Damascus, N/A, Syria; +963 (0)992 647 528; mawiamaherkarkoutly@hotmail.com), ref: N562

Study design
Double-blinded randomized parallel-group active-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bruxism

Interventions
Clinical examination, documentation of participant’s demographic characteristics, and medical history were performed before enrollment. Individuals referred to the Department of Oral and Maxillofacial Surgery underwent an assessment for eligibility. Out of 41 patients, 30 patients were randomly divided into two groups:
Group 1: Bilateral BTX/A injections in the masseter and lateral pterygoid muscles (n = 15)
Group 2: Control group, bilateral BTX/A injections in the masseter muscle only (n = 15)

The injection solution was prepared by mixing the toxin vial (TOXTA, Allergan, Inc., Chicago, United States) with 2 ml of saline serum. Therefore, 50 units of toxin are present in every 1 ml, and 5 units are present in every 0.1 ml. Reference lines for botulinum toxin injection were determined. Regarding the masseter muscle, the anterior and posterior edges of the masseter muscle were drawn by asking the patient to close their teeth tightly and identify the lower edge of the mandible, maintaining a distance of 1 cm from this edge to avoid injury to the marginal branch of the facial nerve. The fourth line was drawn extending from the tragus of the auricle to the commissure by maintaining at least 1 cm away from this line to avoid injury to Stenson's canal and to determine three injection points within the formed rectangle, with an entry depth of 4-6 mm. Regarding the lateral pterygoid muscle, it is beneficial to parallel the needle with the outer ear and push it backwards and sideways to make a 30-degree angle with the plane of occlusion, with an entry depth of 25 - 30 mm. Fifteen units were injected into the masseter muscle at three sites, five units in each site, using a 1 ml syringe with 27G (1 ml-27G-20Pack, XUONFEE STORE US, California, United States), and ten units were injected into the lateral pterygoid muscle utilizing EMG Needle (Technomed Disposable Injectable Needle Length 37 mm, 27 g Orange 10 Pk, Technomed medical accessories, Minnesota, United States).

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Electromyography of the muscles was measured using an electromyography device (2-channel electromyograph MYOQUICK®, Micromed®, Rome, Italy) before treatment (t0) and 2 weeks after treatment (t1). Regarding the masseter muscle, custom gel (EEG Paste, AQUA Medical,

Istanbul, Turkey) was placed on the surface electrodes, with an interval of approximately 3 cm between them, parallel to the fibers of the masseter muscle, in the middle of the muscle, and fixed for accurate measurement. While the ground electrode was placed in the middle of the forehead, its purpose was to distort and remove noise. The patient bit hard on their teeth to clench in the central occlusal position. The measurement was conducted to obtain three values, the highest and the lowest, and the difference was estimated in (μv). Regarding electromyography of the lateral pterygoid muscle, the first surface electrode was placed in front of the ear, the ground electrode was placed in the middle of the forehead, and the EMG Needle was used as a deep electrode for electromyography first, followed by measurement and injection.
2. Bruxism: the participants were asked whether they clenched their teeth during the day or while sleeping and if anyone noticed that they clenched. They were also asked if they had a stiff jaw or facial spasm when they woke up. The questionnaire has four close-ended questions. The scoring was (0) for each no answer and (1) for each yes answer, then presented as a percentage. Patients' answers to the questionnaire were recorded five times before treatment (t0), 2 weeks after treatment (t1), 6 weeks after treatment (t2), 3 months after treatment (t3), and 6 months after treatment (t4).

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
15/11/2024

Eligibility

Key inclusion criteria
1. Patients whose bruxism score was ≥50% according to the Kanathila et al. questionnaire
2. Patients aged 18-40 years
3. Increase in the masseter and lateral pterygoid muscle activity
4. Clinical sign of dental erosion

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
40 years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Pregnant or breastfeeding women
2. Patients receiving therapy such as occlusal splints or previous injections of BTX/A
3. Allergy to BTX/A
4. Severe malocclusion
5. Patients who were undergoing orthodontic treatment
6. Infection at the injection site

Date of first enrolment
03/01/2024

Date of final enrolment
12/02/2024

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Mazzeh
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 datasets generated during and/or analysed during the current study will be available upon request from Dr Mawia Karkoutly (Mawiamaherkarkoutly@hotmail.com). The type of data that will be shared includes anonymised demographic information that will be available after publication. Consent from participants was required and obtained.

IPD sharing plan summary
Available on request