

Evaluating the role of amitriptyline in chronic temporomandibular disorder management: a placebo-controlled trial

Submission date 26/09/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/10/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/03/2025	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The study will aim to assess the effectiveness of low-dose amitriptyline in reducing pain and improving oral health-related quality of life in individuals with chronic temporomandibular disorders (TMD) over 2 months, compared to a placebo.

Who can participate?

Everyone who meets the inclusion criteria will be eligible to participate in the study.

What does the study involve?

Participants will receive either low-dose amitriptyline or a placebo. The study will compare the effects of the medication on pain reduction and quality of life improvement.

What are the possible benefits and risks of participating?

Participants may experience a reduction in pain and an improvement in quality of life. However, the medication may have side effects, including potential mood changes.

Where is the study run from?

School of Dental Medicine, University of Zagreb

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

June 2015 to June 2018

Who is funding the study?

Investigator initiated and funded
Croatian Science Foundation

Who is the main contact?

Iva Ž. Alajbeg, ialajbeg@sfzg.hr

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Prof Iva Ž. Alajbeg

ORCID ID

<https://orcid.org/0000-0001-8524-5661>

Contact details

Gundulićeva 5

Zagreb

Croatia

10000

+38514802125

ialajbeg@sfzg.hr

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

No. IP-2014-09-3070, 643-03/19-02/33

Study information

Scientific Title

Temporomandibular chronic disorder, amitriptyline, splint therapy, pain reduction

Study objectives

Patients taking low-dose amitriptyline will have lower pain and improved quality of life compared to those taking active placebo.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 15/09/2015, Ethics Committee of the University of Zagreb School of Dental Medicine (Petrinjska 34, Zagreb, 10000, Croatia; +385 014802111; dekanat@sfzg.hr), ref: 01-PA-26-6/15

Study design

Interventional double-blind study

Primary study design

Interventional

Study type(s)

Quality of life, Treatment

Health condition(s) or problem(s) studied

Orofacial pain due to chronic temporomandibular disorder

Interventions

Patients will be recruited from the Institute for Mobile Prosthetics, Faculty of Dentistry in Zagreb. Patients with pain lasting longer than 3 months and caused by a temporomandibular disorder will be sought. Patients will sign an informed consent to participate. Two researchers will examine the patients using the Croatian version of the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD). The Visual Analogue Scale (VAS) will be used to determine the intensity of pain, and the Oral Health Impact Profile-14 (OHIP-14) will assess the quality of life. Patients will receive either amitriptyline at a dose of 25 mg or a placebo. The medicine and the placebo will be packed in the medicine factory at random with the help of a computer program in identical bottles with numbers. What is in each bottle will be recorded on a list that the researchers will open at the end of the research. The vial each patient receives is also assigned by a computer program. Patients will be followed up at 4 and 8 weeks, and VAS and OHIP-14 will be measured each time.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Amitriptilin

Primary outcome(s)

The following primary outcome measures will be assessed at baseline and weeks 4 and 8:

1. Pain measured using the Visual Analogue Scale (VAS)
2. Quality of life measured using the Oral Health Impact Profile-14 (OHIP-14)

Key secondary outcome(s)

There are no secondary measures

Completion date

19/06/2018

Eligibility**Key inclusion criteria**

1. Patients aged between 18 and 70 years old
2. Orofacial pain lasting longer than 3 months
3. A VAS outcome above 30 mm
4. Caused by a temporomandibular disorder

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

70 years

Sex

All

Total final enrolment

40

Key exclusion criteria

1. Periodontal diseases
2. Partial dentures
3. Extensive fixed prosthetic works
4. Orthodontic braces
5. Mental or neurological disorders
6. Pregnancy
7. Heart disease
8. Drug allergy

Date of first enrolment

21/09/2015

Date of final enrolment

24/04/2018

Locations**Countries of recruitment**

Croatia

Study participating centre

Faculty of Dentistry in Zagreb, University of Zagreb

Gundulićeva 5

Zagreb

Croatia

10000

Sponsor information

Organisation

University of Zagreb

ROR

<https://ror.org/00mv6sv71>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Funder Name

Croatian Science Foundation

Results and Publications

Individual participant data (IPD) sharing plan

Datasets generated during the study will be available upon request to the researcher, Ratka Borić Brakus, ratka.boric@gmail.com. Research results obtained from statisticians can be obtained.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/03/2025	05/03/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes