ISRCTN17622685 https://doi.org/10.1186/ISRCTN17622685

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

Submission date 26/09/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/10/2024	**Overall study status** Completed	
Last Edited 05/03/2025	**Condition category** Oral Health	

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

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Additional identifiers

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

Primary study design
Interventional

Study design
Interventional double-blind study

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