

Hydrogels with lavender and geranium essential oils for reducing jaw joint pain in patients with temporomandibular joint dysfunction

Submission date 28/10/2025	Recruitment status Recruiting	☒ Prospectively registered ☐ Protocol
Registration date 29/10/2025	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 29/10/2025	Condition category Oral Health	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Many people experience pain or discomfort in the jaw joint, known as the temporomandibular joint (TMJ). This can lead to difficulty chewing, talking, or opening the mouth, and can significantly affect daily life. The aim of this study is to test whether a topical hydrogel containing natural essential oils (lavender and geranium) can help reduce TMJ pain and improve jaw function when applied daily on the skin over the joint.

Who can participate?

Adults over 18 years old who have been diagnosed with temporomandibular joint pain or dysfunction can take part in the study. People who have allergies to any of the gel ingredients or are currently using anti-inflammatory medication can't be included.

What does the study involve?

Participants will apply the study gel once a day over the TMJ area and will be monitored regularly for changes in pain and jaw function. There are four groups in the study: three groups receiving gels with active essential oils and one group receiving a placebo gel without any active ingredients. Pain levels and jaw movement will be evaluated at the beginning of the study and again after 1, 2, and 3 months.

What are the possible benefits and risks of participating?

The study gels may help reduce pain and improve movement of the jaw. The treatment is non-invasive and easy to use at home. Risks are minimal and may include mild skin irritation in rare cases.

Where is the study run from?

The study is being conducted at the Ambulatory Dentistry Clinic of the County Emergency Clinical Hospital in Târgu Mureş, Romania.

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

November 2025 to May 2026

Who is funding the study?

The study is funded by "Dunărea de Jos" University of Galați, Romania.

Who is the main contact?

Dorin Ioan Cocos, cdorin1123@gmail.com

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

40541/21.11.2024 (CEU no. 16/09.12.2024)

Study information

Scientific Title

Controlled-release essential oil hydrogels (geranium, lavender and combination) for pain management in temporomandibular joint dysfunction: a randomized, double-blind, placebo-controlled clinical trial

Acronym

GEO-LEO TMJD

Study objectives

To evaluate the analgesic efficacy and safety of controlled-release hydrogels containing geranium essential oil (GEO), lavender essential oil (LEO), and their combination (GEO+LEO) compared with placebo in the management of chronic pain associated with temporomandibular joint dysfunction (TMJD).

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 09/12/2024, Ethics Committee of 'Dunărea de Jos' University of Galați (47 Domnească Street, Galați, 800008, Romania; +40 (0)236 460 000; Diana.Gheorghe@ugal.ro), ref: 40541/21. 11.2024 (CEU no. 16/09.12.2024)

Study design

Randomized double-blind placebo-controlled parallel-group clinical trial

Primary study design

Interventional

Study type(s)

Efficacy

Health condition(s) or problem(s) studied

Temporomandibular joint dysfunction (TMJD) associated with chronic orofacial pain

Interventions

Participants were randomly assigned to four groups: a hydrogel containing geranium essential oil (H-GEO), a hydrogel containing lavender essential oil (H-LEO), a combined geranium-lavender hydrogel (H-GEO/LEO), and a placebo hydrogel without active ingredients. The formulations were applied topically once daily to the TMJ region for 3 months.

Participants will be randomised in a 1:1:1:1 ratio to four arms (H-GEO/LEO, H-GEO, H-LEO, placebo). The allocation sequence will be computer-generated by an independent statistician using permuted blocks of variable sizes (e.g., 4 and 8), stratified by sex (male/female) and baseline TMJ pain intensity (VAS <5 vs ≥5). Allocation concealment will be ensured via sequentially numbered, opaque, sealed envelopes (SNOSE) prepared off-site by the statistician /pharmacist. After eligibility confirmation and written consent, the investigator enrolls the participant; the pharmacist assigns the next code and dispenses identically packaged interventions.

The trial will be double-blind (participants, investigators, outcome assessors). The randomisation list will be stored securely and only accessible to the independent pharmacist/statistician. Emergency unblinding will follow a predefined SOP and will occur only when knowledge of the assignment is essential for participant safety. Analyses will follow the intention-to-treat principle.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

H-GEO (hydrogel containing geranium essential oil), H-LEO (hydrogel containing lavender essential oil), H-GEO/LEO (combined geranium-lavender hydrogel), and placebo hydrogel (vehicle only)

Primary outcome(s)

Pain intensity measured using the Visual Analog Scale (VAS) at baseline (T0), month 1 (T1), month 2 (T2), and month 3 (T3)

Key secondary outcome(s)

Measured at baseline (T0), month 1 (T1), month 2 (T2), and month 3 (T3):

1. Maximum mouth opening (MMO) measured as part of the modified Helkimo Index using a digital Vernier caliper, recorded as the interincisal distance (mm) between the upper and lower central incisors. MMO values were then scored according to the modified Helkimo scale.
2. Muscle tenderness on palpation is assessed by common bilateral palpation of the masseter, temporalis, medial pterygoid, and other TMJ-associated muscles using approximately 1 kg/cm² of pressure, applied with the fingertips. The number of painful sites is then scored according to the modified Helkimo Index severity scale.
3. TMJ sounds (clicking, crepitus) and mandibular deviation are evaluated through direct clinical observation during mouth opening and closing, following the protocol used in the modified Helkimo Index. The presence or absence of deviation/sounds, as well as locking or dislocation, determines the score.
4. Patient-reported quality of life and functional impairment are assessed using a structured questionnaire based on the anamnestic (AnI) component of the modified Helkimo Index, which evaluates jaw-related discomfort, pain during function, stiffness, and the effect of symptoms on daily activities.
5. Adverse events are monitored continuously throughout the study and documented at each follow-up visit. Any unexpected reactions (e.g., skin irritation or discomfort) are recorded and, if necessary, reported to the safety protocol.

Completion date

31/05/2026

Eligibility**Key inclusion criteria**

1. Diagnosed temporomandibular joint dysfunction (TMJD) according to Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) criteria
2. Aged between 18 and 65 years
3. Chronic TMJ-related pain lasting more than 3 months
4. Baseline visual analogue scale (VAS) pain score $\geq 4/10$
5. Ability to comply with treatment and follow-up visits
6. Signed informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Total final enrolment

112

Key exclusion criteria

1. Previous TMJ surgery
2. Acute infection or trauma of the TMJ area
3. Systemic rheumatologic or autoimmune disorders in active phase
4. Pregnancy or breastfeeding
5. Known allergy to essential oils or hydrogel components
6. Concurrent use of systemic corticosteroids or NSAIDs during trial period
7. Psychiatric or neurological conditions impairing protocol adherence

Date of first enrolment

10/11/2025

Date of final enrolment

10/02/2026

Locations**Countries of recruitment**

Romania

Study participating centre

County Emergency Clinical Hospital Târgu Mureş

Dentistry Outpatient Clinic

50 Gheorghe Marinescu Street

Târgu Mureş

Romania

540136

Sponsor information

Organisation

"Dunarea de Jos" University of Galati

ROR

<https://ror.org/052sta926>

Funder(s)**Funder type**

University/education

Funder Name

Universitatea 'Dunărea de Jos' Galați

Alternative Name(s)

University of Galati, Dunarea De Jos University Of Galati, 'Dunarea de Jos' University of Galati, Univ. Dunarea de Jos Galati, Galati University 'Dunarea de Jos', Dunarea de Jos , Университет „Dunărea de Jos” в Галац, Universitatea „Dunărea de Jos” din Galați, UDJG, DJUG

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Romania

Results and Publications**Individual participant data (IPD) sharing plan**

No individual participant data (IPD) will be shared. Only aggregated and anonymised results may be made available upon reasonable request after publication.

IPD sharing plan summary

Not expected to be made available

Study outputs

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