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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
No longer recruiting

Registration date
29/10/2025

Overall study status
Completed

Last Edited
06/03/2026

Condition category
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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 Mureș, 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 Cocoș, cdorin1123@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Dorin Ioan Cocoș

ORCID ID
https://orcid.org/0009-0003-6823-8138

Contact details
50 Gheorghe Marinescu Street
Târgu Mureș
Romania
540142
+40 (0)748649110
cdorin1123@gmail.com

Additional identifiers

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)

Primary study design
Interventional

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

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Temporomandibular joint dysfunction (TMJD) associated with chronic orofacial pain

Interventions
Current interventions as of 06/03/2026:
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 enrols 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.

All participants received standardized background analgesic care consisting of a diclofenac sodium transdermal patch administered uniformly across all study groups. This was implemented for ethical pain management and was not a variable under investigation.

Previous 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 enrols the participant; the pharmacist assigns the next code and dispenses identically packaged interventions.

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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)
Current primary outcome as of 06/03/2026:
Pain intensity measured using the Visual Analog Scale (VAS) at baseline (T0), 1 week (T1), 1 month (T2), 3 months (T3)

Previous primary outcome:
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
Current key inclusion criteria as of 06/03/2026:
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 pain intensity ≥3 on the Visual Analog Scale (VAS).
5. Ability to comply with treatment and follow-up visits
6. Signed informed consent

Previous 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 ≥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
Mixed

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 Mureș
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

IPD sharing plan summary
Not expected to be made available