Systemic vs. topical Reparil 'Registered Trademark' for the treatment of Temporomandibular Joint and Masticatory Muscle Pain

ACTRN12615000310561

Status	RECRUITING
Phase	Phase 2
Sponsor	Hawler Medical University
Enrollment	50 participants

Plain Language Summary

This study is comparing two forms of a medication called Reparil — one taken as a tablet and one applied as a gel — for treating pain in the jaw joint (temporomandibular joint or TMJ) and the muscles used for chewing. A placebo (dummy treatment) group is also included for comparison. The goal is to find out which form of Reparil works better and is better tolerated.

You may be eligible if:
- You are between 18 and 65 years old
- You have self-reported facial ache or pain in the jaw muscles, jaw joint, or in front of the ear
- You have a clinical diagnosis of a temporomandibular disorder (TMD) based on research diagnostic criteria
- Your jaw joint pain has been present for at least 1 month on most days

You may NOT be eligible if:
- You have infectious arthritis, crystal-induced arthropathy, or another musculoskeletal disorder
- You have a primary diagnosis of myofascial pain
- Your headaches are primarily due to migraine or another specific head pain condition
- You have an active infection in your teeth, ears, eyes, nose, or throat
- You have untreated depression or unstable antidepressant medication
- You have dental disease requiring ongoing treatment
- You are pregnant or breastfeeding
- You are sensitive to any ingredient in Reparil

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (3)

- Self report of facial ache or pain in the muscles of mastication, the TMJ, or the region in front of ear or inside the ear
- Positive clinical diagnosis of TMDs. The TMD diagnosis is classified using axis I of the research diagnostic criteria (RDC) for TMDs. The RDC diagnosis consists of joint pain at rest (spontaneous pain) and evoked pain (hyperalgesia) on palpation of the TMJ, TMJ reduction consists of reciprocal clicking or joint noise with mandibular movement examination.
- For joint pain complaint, subjects will be required to have a self-report of at least 1 month of daily or nearly daily pain.

Exclusion (7)

- Subjects with infectious arthritis, crystal induced arthropathies, musculoskeletal disorders, subjects with a primary diagnosis of myofascial pain based on the RDC;
- Subjects with pain attributable to confirmed migraine or head pain condition other than tension headache;
- Subjects with acute infection or other significant disease of teeth, ears, eyes, nose or throats; subjects with untreated depressive disorder or not on stable antidepressant medication for more than 6 months;
- Subjects with dental diseases that required ongoing treatment, which would confound the evaluation of orofacial pain;

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- Subjects who are not competent in giving consents.

... and 2 more (see full listing online)

Locations (1 total)

Iraq

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