

Efficacy of Gou-Teng-San (GTS) in Patients With Episodic Migraine: A Double-Blind Randomized Controlled Trial

NCT07496034

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| Status | RECRUITING |
| Phase | Phase 3 |
| Sponsor | Tsai, Chueh-Yi, MD |
| Enrollment | 40 participants |

Key Eligibility Criteria

Inclusion (9)

- Adults aged 18 to 70 years.
- History of episodic migraine for at least 12 months before screening, meeting the International Classification of Headache Disorders, 3rd edition (ICHD-3) criteria, or clinically diagnosed migraine with no more appropriate ICHD-3 diagnosis.
- During the 28-day screening period, participants must meet criteria for episodic migraine, defined as headache occurring on ≥ 6 and ≤ 14 days, of which ≥ 4 days meet at least 1 of the following: (1) ICHD-3 criteria C and D for 1.1 migraine without aura; (2) ICHD-3 criteria B and C for 1.2 migraine with aura; (3) probable migraine (missing 1 migraine criterion); or (4) headache considered to be migraine based on a positive response to migraine-specific acute treatment (e.g., a triptan or an ergotamine derivative).
- Not receiving preventive migraine medication for at least 5 half-lives before enrollment, or receiving no more than 1 preventive migraine medication at a stable dose and regimen for at least 2 months before informed consent, whether for migraine or another medical condition (e.g., propranolol for hypertension).
- Body mass index (BMI) between 17.5 and 37.5 kg/m², and body weight between 35 and 120 kg.

... and 4 more (see full listing online)

Exclusion (12)

- Known allergy or hypersensitivity to Gou-Teng-San or any of its ingredients.
- Receipt of botulinum toxin type A injections in the head, face, or neck for any reason within 4 months before screening.
- Use of opioid-containing or barbiturate-containing medications on more than 4 days per month.
- Lack of efficacy after at least 3 months of treatment at accepted migraine treatment doses in 2 or more of the following preventive medication classes: (1) topiramate or valproic acid; (2) flunarizine; (3) amitriptyline, venlafaxine, or duloxetine; (4) atenolol or propranolol.
- Use of migraine treatment interventions within 2 months before screening, such as nerve block or transcranial magnetic stimulation.

... and 7 more (see full listing online)

Locations (1 total)

Chung Shan Medical University Hospital, Taichung, South, Taiwan

<https://clinicaltrials.gov/study/NCT07496034>

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