

Efficacy and Safety of CDE100 in the Treatment of Menstrual Cramp Pain Associated With Primary Dysmenorrhea

NCT05640232

Status	RECRUITING
Phase	Phase 3
Sponsor	EMS
Enrollment	238 participants

Key Eligibility Criteria

Inclusion (5)

- Patient has given written informed consent to participate in the study prior to admission to the study;
- Female patients aged between 16 and 35 years old, inclusive;
- History of regular menstrual cycles, occurring between every 21 to 35 days;
- Clinical history compatible with the diagnosis of primary dysmenorrhea;
- Self-reported history of e 4 painful cycles, with moderate or severe menstrual cramps, in the six (06) months prior to selection for the study.

Exclusion (27)

- Diagnosis of secondary dysmenorrhea;
 - History of non-response to treatment with non-steroidal anti-inflammatory drugs (NSAIDs) to relieve menstrual cramps;
 - Onset of primary dysmenorrhea after starting to use oral contraceptives;
 - Use of oral contraceptives for \< 3 months prior to study selection;
 - Use of an intrauterine device (IUD), hormonal implants or contraceptive injections in the last six (06) months;
- ... and 22 more (see full listing online)

Locations (1 total)

EMS, Hortolândia, São Paulo, Brazil