

A Phase IIa Clinical Study to Assess the Efficacy and Safety of GenSci048 in Patients With Moderate to Severe Endometriosis-Associated Pain

NCT06963177

Status	RECRUITING
Phase	Phase 2
Sponsor	Changchun GeneScience Pharmaceutical Co., Ltd.
Enrollment	200 participants

Key Eligibility Criteria

Inclusion (6)

- Pre-menopausal female participants, between 18 and 49 years of age, inclusive, at the time of signing informed consent.
- Participants must have a diagnosis of endometriosis within 10 years before screening.
- Have moderate to severe endometrial related pain.
- Have at least one regular, natural menstrual cycles (ranging from 21 to 35 days (inclusive)) before and during the screening period.
- Agree to switch from her usual analgesic medication to only that which is permitted in the study from the screening period to the end of treatment and agree to stop using other treatments for endometriosis.

... and 1 more (see full listing online)

Exclusion (10)

- Participants who have previously received hysterectomy and/or bilateral oophorectomy, or plan to undergo these procedures during the study period.
- Participants who suffer from chronic pelvic and/or non-pelvic pain that is not caused by EM and require chronic analgesia or other chronic treatment, which is expected to affect the assessment of EAP.
- Pelvic ultrasound screening indicating a need for surgery or suspicion of malignancy.
- Participants with abnormal and undiagnosed vaginal and/or uterine bleeding within 3 months prior to screening.
- Participants who plan to schedule elective surgery during the study; or those who have had a surgery within 4 months prior to screening and need ongoing pain management.

... and 5 more (see full listing online)

Locations (1 total)

Peking University First Hospital, Beijing, Beijing Municipality, China