Evaluation of the Analgesic Effect of Intramyometrial Botulinum Toxin Injection Via Hysteroscopy in Severe Primary Dysmenorrhea

NCT06995287

Status	RECRUITING
Phase	Phase 3
Sponsor	Nantes University Hospital
Enrollment	222 participants

Key Eligibility Criteria

Inclusion (7)

- Adult women who are not menopausal,
- Experiencing severe dysmenorrhea, defined as an average pain intensity score e 6/10 on a Numerical Rating Scale (NRS) over the past 3 months at the inclusion visit,
- Having failed optimal first-line medical treatment combining hormonal therapy and appropriate analgesics (Level I and II analgesics, and NSAIDs),
- Having undergone a pelvic MRI within 6 months prior to the inclusion visit that shows no evidence of deep infiltrating endometriosis or endometrioma, following systematic review by radiologists from the expert center managing the patient (if the pelvic MRI is deemed of insufficient quality for interpretation, a new MRI will be performed at the center),
- Using a highly effective method of contraception (failure rate \<1%) for the entire duration of the follow-up period. Highly effective contraception methods are defined as one of the following: combined hormonal contraception (containing estrogen and progestin) with ovulation inhibition (oral, vaginal, or transdermal), progestin-only hormonal contraception with ovulation inhibition (oral, injectable, or implantable), intrauterine device (IUD), intrauterine hormonal system (IUS), condoms, bilateral tubal occlusion, vasectomized partner, or sexual abstinence,

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

Exclusion (14)

- Pregnant or planning a pregnancy during the entire study period,
- Currently breastfeeding,
- Refusal to use effective contraception during the study and for 6 months after its completion,
- Contraindications to botulinum toxin, including:
- Generalized disorders of muscular activity (e.g., myasthenia gravis, Lambert-Eaton syndrome),

... and 9 more (see full listing online)

Locations (8 total)

Clinique axium / Centre resilience, Aix-en-Provence, France
CHU Angers, Angers, France
CHU Brest, Brest, France
... and 5 more locations