

Effectiveness of Low-dose Naltrexone in Patients With Different Types of Vulvodynia

NCT05955313

Status	RECRUITING
Phase	Phase 2
Sponsor	Medical University of Lublin
Enrollment	300 participants

Key Eligibility Criteria

Inclusion (10)

- Women from the age of 18 to the menopause or to the age of 50 (on the day of inclusion for testing).
- Patients who are not pregnant and do not plan to become pregnant in the next 9 months from the inclusion in the study
- Signing the patient's informed and voluntary consent to participate in the study.
- General health of the patient (WHO = 0-2).
- Diagnosis of vulvodynia.

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

Exclusion (13)

- Severe, hepatic and renal dysfunction defined as:
 - i. An ASPT or ALT result 5 times the upper limit; ii. The level of bilirubin 3 times above the upper limit of normal - excluding patients with Gilbert's syndrome; iii. EGFR result below 30 ml / min / m², on the basis of historical studies not older than 3 years before the screening visit or from the tests performed during the screening visit according with point 12 of the Protocol, version 1.0 of March 28, 2022.
- Abuse of alcohol (more than 14 units per week) and other stimulants. 3. Taking psychoactive substances, including drugs, except for SSRI, SNRI, SARI (Trazodone), and anticonvulsants (Gabapentin, Pregabalin, Lamotrigine) in fixed doses from the screening visit.
- \. Taking opioid drugs in the last 2 months before the screening visit (also in OTC preparations, eg Loperamide).
- \. Taking naltrexone hydrochloride and Mysimba for weight loss at any time in your life.

... and 8 more (see full listing online)

Locations (1 total)

Terpa Limited Liability Company Limited Partnership, Lublin, Poland