

A GnRH Agonist IN Pre-menopausal Women Study to Treat Severe Polycystic Liver Disease

NCT05478083

Status	RECRUITING
Phase	Phase 2
Sponsor	University Medical Center Groningen
Enrollment	36 participants

Key Eligibility Criteria

Inclusion (14)

- Female patients
- Diagnosis of polycystic liver disease defined as the presence of more than 10 liver cysts
- Age between 18 to 45 (inclusive) years;
- Very large liver for age, defined as the upper 10% of liver volumes in specific age categories (based on a retrospective polycystic liver disease registry, n=1.600 patients)
- yr; height adjusted TLV \geq 2.0 L/m
- ... and 9 more (see full listing online)

Exclusion (10)

- Post-menopausal status or (vasomotor) symptoms indicating upcoming menopause
- Anti Mullerian Hormone (AMH) measurement at screening visit $<$ 0.03 ng/ml.
- Active desire to have children, pregnancy or breast-feeding
- Contra-indications for leuprorelin, such as history of cardiovascular disease, history of osteoporosis or osteoporosis determined by DEXA-scan at screening (T score \leq -2.5), or a known intolerance for leuprorelin
- Liver transplantation or liver surgery expected within 1.5 years, to the discretion of the study doctor
- ... and 5 more (see full listing online)

Locations (2 total)

Radboudumc, Nijmegen, Gelderland, Netherlands
Groningen universitair medical center, Groningen, Netherlands

<https://clinicaltrials.gov/study/NCT05478083>

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