Darbepoetin in Patients Candidates for Liver Transplant. (EPO-LT Trial)

NCT07169643

Status	RECRUITING
Phase	Phase 3
Sponsor	Fundacion Clinic per a la Recerca Biomédica
Enrollment	140 participants

Key Eligibility Criteria

Inclusion (5)

- Age e 18 years old
- Patients on the official liver transplant waiting list
- Hemoglobin (Hb) level d 11.5 g/dL
- Women of child-bearing potential* must have a negative pregnancy test in serum before the inclusion in the study and agree to use highly effective contraceptive methods during the study. Highly effective contraceptive methods will include: intrauterine device, bilateral tubal occlusion, vasectomized partner and sexual abstinence** (only if refraining from heterosexual intercourse during the period of twelve months). Hormonal contraceptive methods will be avoided due to the risk of adverse events and impairment of liver function.
- A woman will be considered of childbearing potential, following menarche and until becoming post-menopausal unless permanently sterile. Permanent sterilization methods include hysterectomy, bilateral salpingectomy and bilateral oophorectomy. A postmenopausal state is defined as 0 menses for 12 months without an alternative medical cause. A high follicle stimulating hormone level in the postmenopausal range may be used to confirm a postmenopausal state in women not using hormonal contraception or hormonal replacement therapy. However, in the absence of 12 months of amenorrhea, a single follicle stimulating hormone measurement is insufficient. ** Sexual abstinence should only be used as a contraceptive method if it is in line with the subjects' usual and preferred lifestyle. Periodic abstinence (calendar, symptothermal, post ovulation methods) is not an acceptable method of contraception.

Exclusion (1)

- \. Acute/subacute liver failure (see appendix 7) 2. Patients with acute-on-chronic liver failure grade III and/or MELD \> 35 3. History of thrombosis, including portal vein thrombosis 4. Significant coronary artery disease (requiring angioplasty and/or coronary stent) 5. Serum ferritin \> 800 ng/mL and SAT \> 50% 6. Anticoagulant/antiplatelet therapy 7. History of seizures 8. Uncontrolled hypertension (requiring e2 antihypertensive drugs) 9. Active infection/sepsis (see appendix 8) 10. Lack of patient consent. 11. Pregnancy or breastfeeding. 12. Patients included in other clinical trials in the month before inclusion. 13. Patients with mental incapacity, language barrier, bad social support or any other reason considered by the investigator precluding adequate understanding, cooperation or compliance in the study.

Locations (1 total)

Hospital Clinic de Barcelona, Barcelona, Catalonia, Spain