Oral Propranolol for Prevention of Threshold Retinopathy of Prematurity

NCT03083431

Status	RECRUITING
Phase	Phase 2
Sponsor	University of Zurich
Enrollment	276 participants

Key Eligibility Criteria

Inclusion (6)

- Preterm infant born before 28 week's gestation
- Birth weight below 1250 g
- At least 5 weeks of age (at randomisation)
- PMA 310/7 - 36 6/7 weeks
- Ophthalmoscopic evidence of incipient ROP (stage 1 or 2, with or without plus disease in any zone)

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

Exclusion (14)

- ROP stage e 3, AP-ROP or suspected AP-ROP, or any other ROP requiring an intervention (study endpoint already reached).
- Conditions that indicate open label propranolol such as: thyrotoxicosis, arterial hypertension or certain heart diseases (such as tetralogy of Fallot, paroxysmal supraventricular tachycardia, or long QT syndrome) etc.
- Major congenital malformations or known chromosomal anomalies
- Colobomas and other eye malformations
- PHACE syndrome (posterior fossa anomalies, large infantile hemangiomas of the face, neck, and/or scalp, arterial lesions, cardiac abnormalities/coarctation of the aorta, eye anomalies) (risk of cerebrovascular complications)

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

Locations (3 total)

University Hospital Tübingen, Tübingen, Baden-Wurttemberg, Germany
University Hospital Zurich, Zurich, Canton of Zurich, Switzerland
Ankara University School of Medicine Children's Hospital, Ankara, Ankara, Turkey (Türkiye)