

# Safety and Efficacy of Propranolol in Newborns With Retinopathy of Prematurity (PROP-ROP)

<b>Submission date</b> 06/06/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 12/07/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/01/2014	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT01079715

**Clinical Trials Information System (CTIS)**  
2010-018737-21

**Protocol serial number**  
EudraCT Number

# Study information

## Scientific Title

Evaluating the safety and efficacy of propranolol administration in preterm newborns suffering from a precocious phase of retinopathy of prematurity (ROP): A randomised controlled trial

## Acronym

PROP-ROP

## Study objectives

To evaluate the safety of propranolol administration in preterm newborns suffering from a precocious phase of retinopathy of prematurity (ROP) and its efficacy to reduce the disease progression, the incidence retinal detachment and of blindness, by suppressing the neovascular phase of ROP compared to a control group receiving conventional treatment.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

The Centre Research Ethics Board (Comitato Etico Sperimentazione dei Medicinali [CESM]) of A. Meyer University Children's Hospital, Florence and of the Institute of Pediatrics and Neonatology, Fondazione IRCCS Ospedale Maggiore Policlinico, Mangiagalli e Regina Elena, University of Milan approved on the 14th of January 2010 (ref: 277/2010).

## Primary study design

Interventional

## Study design

Interventional randomised active controlled parallel group trial

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Retinopathy of prematurity (ROP), the leading cause of blindness in children

## Interventions

Parents of newborns who meet the inclusion criteria will be approached by the study investigator/nurse, informed of the study. Signed written informed consent will be obtained. Patients will be randomised to receive:

1. Intervention: Administration of propranolol. Dosage of 0.5mg/Kg orally, every 6 hours in the treated arm. This treatment will be continued until vascularization of retina will be complete.
2. Control: Treatment as usual. Standard laser therapy.

## Intervention Type

Other

## Phase

Phase II

**Primary outcome(s)**

To evaluate the safety of propranolol administration in preterm newborns suffering from a precocious phase of ROP.

In order to evaluate the safety of this treatment, heart frequency, blood pressure, oxygen saturation, respiratory support, will be continuously monitored.

Blood samplings to check renal, liver and metabolic balance will be performed weekly for the first 4 weeks of treatment.

**Key secondary outcome(s)**

To evaluate the safety of propranolol administration in preterm newborns suffering from a precocious phase of ROP.

In order to evaluate the efficacy of this treatment, serial ophthalmologic evaluations will be planned at different intervals according to the severity of ROP. The efficacy will be evaluated comparing the different incidence of the progression of ROP to stages 3 or to retinal detachment, the different incidence of laser treatment, the different incidence of vitrectomy, between the two groups.

The follow-up planned at 1, 4 and half, 6, 12, 18 and 24 months, will allow to evaluate the functional outcome.

Visual acuity will be evaluate at 1, 4 and half, and 12 months of corrected age.

**Completion date**

31/12/2011

**Eligibility****Key inclusion criteria**

The studied population consists of preterm infants delivered at less than 32 weeks gestational age admitted to the Neonatal Intensive Care Unit at the A. Meyer University Children's Hospital, Florence and at the Institute of Pediatrics and Neonatology, Fondazione IRCCS Ospedale Maggiore Policlinico, Mangiagalli e Regina Elena, University of Milan.

1. Infants who have been screened for ROP ( $\geq 32$  weeks gestation) who developed zone II-III, stage 2 ROP without plus.
2. Informed Consent from a parent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Neonate

**Sex**

All

**Key exclusion criteria**

1. Newborns with congenital cardiovascular anomalies, renal failure, cerebral haemorrhage, which contraindicate the use of beta-blockers
2. Newborns with ROP stages more advances than zone II-III, stage 2 ROP without plus

3. Informed Consent from a parent refused. This will mean that an infant automatically will receive standard laser therapy. No data will be used from an infant without Informed Consent.

**Date of first enrolment**

01/01/2010

**Date of final enrolment**

31/12/2011

## **Locations**

**Countries of recruitment**

Italy

**Study participating centre**

**Neonatal Intensive Care Unit**

Florence

Italy

I-50139

## **Sponsor information**

**Organisation**

A. Meyer University Children's Hospital (Italy)

**ROR**

<https://ror.org/01n2xwm51>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

A. Meyer University Children's Hospital (Italy)

**Funder Name**

Fondazione Istituto Di Ricovero e Cura a Carattere Scientifico (IRCCS) Ospedale Maggiore Policlinico, Mangiagalli e Regina Elena (Italy)

**Funder Name**

University of Milan (Italy)

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/12/2013		Yes	No
<a href="#">Protocol article</a>	protocol	18/11/2010		Yes	No