

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Luca Filippi

Contact details
Neonatal Intensive Care Unit
Department of Critical Care Medicine
A. Meyer University Childrens Hospital
Viale Pieraccini 24
Florence
Italy
I-50139

Additional identifiers

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

ClinicalTrials.gov (NCT)
NCT01079715

Protocol serial number
EudraCT Number 2010-018737-21

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).

Study design

Interventional randomised active controlled parallel group trial

Primary study design

Interventional

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 (≥ 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?
Results article	results	01/12/2013		Yes	No
Protocol article	protocol	18/11/2010		Yes	No