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

Submission date 06/06/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/07/2010	**Overall study status** Completed	
Last Edited 29/01/2014	**Condition category** Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes