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Risk factors in retinopathy of prematurity

Submission date	Recruitment status	[_] Prospectively registered
05/07/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/07/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/08/2019	Eye Diseases	

Plain English summary of protocol

Background and study aims
In the womb, the retina (light sensitive patch at the back of the inside of the eye that converts images into a form that the brain can understand) develops slowly and the blood vessels in the retina (retinal blood vessels) often only complete growing by the end of gestation. If a child is born prematurely, these blood vessels can grow abnormally. This can cause damage to the retina and affect the sight of the baby. This is called retinopathy of prematurity (ROP). Knowing what is more likely to cause ROP (that is, risk predictors) will help to prevent and manage the condition. The aim of this study is to identify maternal (mother) and neonatal (baby) risk predictors of ROP in very low birth weight neonates.

Who can participate?
Premature babies of very low weight and their mothers.

What does the study involve?
Once they are born, babies undergo ROP screening by an experienced ophthalmologist. Each baby is allocated to either the case group (if they have ROP) or control group (if they don't have ROP). Data is then collected in order to assess potential risk predictors of ROP. Possible maternal risk predictors looked at include, amongst others, type of delivery, maternal fever, gestational diabetes mellitus, heart disease and infertility treatment. Possible neonatal risk predictors looked at include, among others, gestational age, birth weight, low blood pressure, whether they have problems with breathing and whether they need oxygen therapy. A statistical analysis is then carried out to see whether there are some risk predictors that are more likely to cause ROP.

What are the possible benefits and risks of participating?
There are no direct benefits to the participants but identification of risk factors will help to prevent ROP in the future. The study in no way shall be harmful to the participants.

Where is the study run from?
Government Medical College, Trivandrum (India)

When is the study starting and how long is it expected to run for?
November 2008 to April 2010

Who is funding the study?
Government Medical College, Trivandrum (India)

Who is the main contact?
Dr Sheena Perumbil

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
07/06/2008/MCT

Study information

Scientific Title
Risk predictors for the development of retinopathy of prematurity in very low birth weight neonates

Study objectives
To evaluate risk factors for development of retinopathy of prematurity in preterm very low birth weight neonates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Ethical Committee, Medical College, Thiruvananthapuram, 14/11/2008, ref: IEC No: 07/06 /2008/MCT

Study design
Prospective unmatched case control study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Retinopathy of prematurity in very low birth weight neonates

Interventions
The study aimed to evaluate risk factors for development of retinopathy of prematurity in preterm very low birth weight neonates. The study was a prospective, unmatched case control study conducted in a tertiary care centre in Kerala, India that was commenced after obtaining approval from the Institutional Ethics Committee.

The study was conducted in subjects admitted in the neonatal intensive care unit (NICU) after obtaining written informed consent. The cases and controls for the study were defined as follows:
1. Cases: preterm babies admitted in the NICU with a birth weight <1500 g and with a gestational age < 34 weeks who developed retinopathy of prematurity of any severity.
2. Controls: preterm babies admitted in NICU with a birth weight <1500g and < 34 weeks of gestational age who did not develop retinopathy of prematurity.

All the preterm babies who were admitted in the inborn nursery satisfying the study criteria were referred to the Department of Ophthalmology in the same hospital at 4 weeks of postnatal age. Screening for retinopathy of prematurity was done by an experienced ophthalmologist and interventions were carried out according to the degree of severity and follow up examinations were done until the resolution of ROP. The study was conducted for a period of 18 months and various maternal and fetal risk factors for development of ROP were analysed. Need for oxygen support, duration and mode of oxygen administration were noted.

Screening for ROP: In the Department of Ophthalmology an experienced ophthalmologist was in charge of ROP screening.

Statistical analysis: The quantitative variables under the study were described by mean with its 95% confidence intervals and qualitative variables with frequencies and proportions. Chi-square test was used in case of qualitative variables. Binary logistic regression was used to find out independent predictors of the outcome. The odds ratio with its confidence given by the model was taken as the strength of association in the final analysis. Based on a previous study the odds ratio of low gestational age for the development of ROP in the premature babies was 3.1.

Intervention Type
Other

Primary outcome(s)
Occurrence of retinopathy of prematurity (ROP) in very low birth weight neonates (<1500g and <34 weeks of age) at four weeks of postnatal age. The screening was conducted by an experienced ophthalmologist

Key secondary outcome(s))

Assessment of a significant association between ROP and both maternal and neonatal risk predictors, via statistical analysis at 18 months from start of the study.

Maternal risk predictors: type of delivery, maternal fever, Pregnancy Induced Hypertension (PIH), Gestational Diabetes Mellitus (GDM), cardiac disease, Premature Rupture of Membrane (PROM), antepartum hemorrhage, chorioamnionitis, multiple pregnancy, infertility treatment, urinary tract infections (UTI), polyhydramnios and oligohydramnios.

Neonatal risk predictors: gestational age, birth weight, septicemia, apnoea, anemia, hypotension, need for inotropic support, type and duration of oxygen therapy, patent ductus arteriosus (PDA), necrotizing enterocolitis (NEC), intraventricular hemorrhage (IVH) and phototherapy.

Completion date
01/04/2010

Eligibility

Key inclusion criteria
Preterm babies weighting less than 1.5 kg and gestational age < 34 weeks.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Total final enrolment
108

Key exclusion criteria
Neonates with congenital anomalies

Date of first enrolment
14/11/2008

Date of final enrolment
13/11/2009

Locations

Countries of recruitment
India

Study participating centre
Government Medical College, Trivandrum
Kerala 695011
India
695011

Sponsor information

Organisation
Trivandrum Medical College

ROR
https://ror.org/007fenw03

Funder(s)

Funder type
University/education

Funder Name
Trivandrum Medical College

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/03/2017	09/08/2019	Yes	No
Participant information sheet		08/06/2016	26/07/2016	No	Yes