ISRCTN18040926 https://doi.org/10.1186/ISRCTN18040926

Diagnosis and complications of retinal vascular disease developing in preterm children

Submission date	Recruitment status	[_] Prospectively registered
15/07/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/07/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/11/2019	Eye Diseases	

Plain English summary of protocol
Background and study aims
Babies born prematurely have a very low birth weight. In Turkey, 25,000 very low weight babies are born annually, with around 1000 of them facing the risk of blindness (retinopathy of prematurity (ROP)).
The likelihood of these babies developing ROP is affected by the treatment and follow-up that they receive, along with any complications. We retrospectively reviewed the treatment, follow-up period and treatment complications of 302 premature, low birth weight babies who were examined for ROP at SBÜ Bursa YİEAH ROP between the dates of February 2016 to February 2017, to determine the effects of treatment and complications of ROP and demonstrate that complete rehabilitation can be achieved with strict follow-up and appropriate treatment.

Who can participate?
Premature babies, born between 6 and 35 weeks of gestation

What does the study involve?
There is no direct participation for infants involved in the study. Instead, this is a retrospective review of the treatment, follow-up period and treatment complications of participants.

What are the possible benefits and risks of taking part?
The possible benefit of taking part is that it may help prevent severe vision loss in future premature babies. There are no known risks to participants taking part in this study.

Where is the study run from?
SBU Bursa Yüksek İhtisas Training and Research Hospital, Bursa, Turkey

When is the study starting and how long is it expected to run for?
1st July 2018 to 15th July 2018

Who is funding the study?
1. Social Security Institution (Turkey)
2. SBU Bursa Yüksek İhtisas Training and Research Hospital (Turkey)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
7929783.v1

Study information

Scientific Title
Diagnosis, treatment and complications of retinopathy of prematurity

Acronym
ROP

Study objectives
To determine the effects of diagnosis, treatment and complications of retinopathy of prematurity and demonstrate that complete rehabilitation can be achieved with strict follow-up and appropriate treatment of severe ROP

Ethics approval required
Old ethics approval format

Ethics approval(s)
SBU Bursa Higher Specialized Education Research Hospital, 01/07/2018, 31234050-514.10

Study design
Observational cross sectional retrospective review

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Retinopathy of prematurity

Interventions
Records were reviewed, using the International Classification of Retinopathy of Prematurity (ICROP) criteria to review diagnoses and the Early Treatment of Retinopathy of Prematurity (ETROP) study group criteria to review treatments.

Intervention Type

Mixed

Primary outcome measure
The following were measured from birth to the end of the follow-up period:
1. Total maturation of retinal vascularisation
2. IVB (intravitreal bevacizumab) dose
3. LPC (laser photocoagulation) treatment
4. Complications after treatment
5. Stage of ROP
6. Gender of infant
7. Follow-up duration (weeks)
8. Gestational week of birth
9. Incubation duration (days)

Secondary outcome measures
N/A

Overall study start date
01/07/2018

Completion date
15/07/2018

Eligibility

Key inclusion criteria
Preterm babies born between 6 and 35 weeks of gestation

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
Various ROP stages were observed in 118; no ROP was observed in 184. Infants with and without ROP

Key exclusion criteria
N/A

Date of first enrolment
01/02/2016

Date of final enrolment
01/02/2017

Locations

Countries of recruitment
Türkiye

Study participating centre
Department of Ophthalmology, University of Health Sciences (SBU) Bursa Yüksek İhtisas Training and Research Hospital, Bursa, Turkey
SBÜ Bursa Yüksek İhtisas Eğitim ve Araştırma Hastanesi
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Sponsor information

Organisation
Department of Ophthalmology, University of Health Sciences (SBU) Bursa Yüksek İhtisas Training and Research Hospital, Bursa, Turkey

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Sponsor type
Government

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ROR
https://ror.org/05nhkt138

Funder(s)

Funder type
Not defined

Funder Name
Absent

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
02/08/2018

Individual participant data (IPD) sharing plan
Retinal images (if available) and clinical follow-up information without the patient's identity information can be obtained from mbrakdogan@yahoo.com.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/03/2015		Yes	No
Participant information sheet			02/04/2019	No	Yes