

# Diagnosis and complications of retinal vascular disease developing in preterm children

<b>Submission date</b> 15/07/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/07/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/11/2019	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

## 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?

1. Müberra Akdoğan (mbrakdogan@yahoo.com)
2. Görkem Çevik (gorkemcevic@hotmail.com)

## Contact information

### Type(s)

Scientific

### Contact name

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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

Mimarsinan Mahallesi, No:, Emniyet Cd. No:35, 16310 Yıldırım/Bursa

BURSA

Türkiye

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# Sponsor information

## Organisation

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

## Sponsor details

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## Sponsor type

Government

## Website

[bursaihtisas.saglik.gov.tr](http://bursaihtisas.saglik.gov.tr)

## 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?
<a href="#">Results article</a>	results	08/03/2015		Yes	No
<a href="#">Participant information sheet</a>			02/04/2019	No	Yes