

# The role of inflammation in the outcomes of retinopathy of prematurity

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<b>Registration date</b> 14/08/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/08/2020	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Retinopathy of prematurity (ROP) is a disease caused by abnormal development of the blood vessels in premature (born early) infants. This can mean loss of function of the retina, the inner layer of the eye that receives light and turns it into visual messages that are sent to the brain. ROP can in some cases lead to blindness. Steroids given to mothers who are likely to give birth prematurely can reduce the chance of complications of prematurity such as ROP.

Recent studies report that inflammation is associated with retinopathy of prematurity (ROP). In addition, it has been revealed that general inflammation can lead to problems with retinal blood vessel development and symptoms of ROP in newborn animals. This trial aims to see if measuring levels of inflammation (using levels of white blood cells as a marker of inflammation) can predict the likelihood and severity of ROP.

### Who can participate?

Data will be collected from premature infants (born before 35 weeks gestation)

### What does the study involve?

This is an observational trial. All information will be obtained from the patient's hospital file and there will be no changes to patient care as part of the study. The information collected will be: whether the participants had developed ROP; and the complete blood count (CBC) from blood samples taken within 72 hours of birth and one month after birth.

### What are the possible benefits and risks of participating?

This is an observational trial so there are no anticipated risks with participation.

### Where is the study run from?

Bursa Yuksek Ihtisas Education And Research Hospital (Turkey)

### When is the study starting and how long is it expected to run for?

From February 2016 to February 2018

Who is funding the study?  
National Institutes of Health (USA)

Who is the main contact?  
Prof Muberra Akdogan  
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## Contact information

**Type(s)**  
Public

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
Nil known

## Study information

**Scientific Title**  
Correlation between Systemic Immun-Inflammation index and routine hemogram related inflammatory markers in prognosis of Retinopathy Of Prematurity (SII ROP)

**Acronym**  
SII ROP

## **Study objectives**

To evaluate the prognostic potential of the systemic immune-inflammation index in patients with retinopathy of prematurity (ROP).

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 09/06/2018, Bursa Yuksek Ihtisas Education And Research Hospital Clinical Research Ethics Committee (Mimar Sinan Mah. Emniyet Cad. Yıldırım, Bursa, 16310 Turkey; +90 (0)224 295 52 83), ref: 2011-KAEK-25 2018/09-06.

## **Study design**

Retrospective cohort study

## **Primary study design**

Observational

## **Secondary study design**

Cohort study

## **Study setting(s)**

Hospital

## **Study type(s)**

Diagnostic

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet.

## **Health condition(s) or problem(s) studied**

Retinopathy of prematurity

## **Interventions**

There is no intervention as this is an observational trial. All data will be obtained from the patient's hospital file for premature participants without ROP, and with early-stage ROP, aggressive posterior ROP (APROP), and advanced stage ROP. The data collected will be whether the participants had developed ROP and Complete blood count (CBC) at birth and one month after birth. The CBC will be used to calculate the Serum neutrophil-to-lymphocyte ratio (NLR), lymphocyte-to-monocyte ratio (LMR), platelet-to-lymphocyte (PLR) and Systemic Immune-inflammation Index (SII) for participants at birth and one month after. LMR was calculated by dividing the absolute lymphocyte count by the absolute monocyte count. NLR and PLR were determined by dividing the absolute neutrophil count or the absolute platelet count by the absolute lymphocyte count, respectively. The SII was calculated by the dividing the product of the absolute neutrophil count and the absolute platelet count by the absolute lymphocyte count.

## **Intervention Type**

Not Specified

## **Primary outcome measure**

Significance of Systemic Immune-inflammation Index (SII) values in the development period of ROP measured from Complete blood count (CBC) at birth and one month after birth

### **Secondary outcome measures**

Prediction of the development of ROP using white blood cell (WBC) ratios such as neutrophil-to-lymphocyte ratio (NLR), lymphocyte-to-monocyte ratio (LMR), platelet-to-lymphocyte (PLR) and Systemic Immune-inflammation Index (SII) values measured from Complete blood count (CBC) at birth and one month after birth

### **Overall study start date**

01/07/2016

### **Completion date**

01/06/2018

## **Eligibility**

### **Key inclusion criteria**

1. Complete blood counts (CBC) measured both <72 h after birth and one month after birth
2. Delivered at gestational age of  $\leq 35$  weeks

### **Participant type(s)**

Patient

### **Age group**

Child

### **Sex**

Both

### **Target number of participants**

303 infants

### **Key exclusion criteria**

1. Sepsis proven in blood culture
2. Necrotizing enterocolitis
3. Hematological disease
4. Receiving blood product transfusion or steroid treatment

### **Date of first enrolment**

01/05/2016

### **Date of final enrolment**

01/02/2018

## **Locations**

### **Countries of recruitment**

Türkiye

**Study participating centre****Bursa Yuksek Ihtisas Education and Research Hospital**

Mimar Sinan, No:  
Emniyet Cd. No:35  
Bursa  
Türkiye  
16310

**Study participating centre****Afyonkarahisar Health Sciences University Hospital**

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Dortyol Mah. 2078 Sok. No3  
Afyon  
Türkiye  
03200

## **Sponsor information**

**Organisation**

Bursa Yuksek Ihtisas Education And Research Hospital

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<https://bursayuksekihtisaseah.saglik.gov.tr/>

**ROR**

<https://ror.org/05nhkt138>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

National Institutes of Health

**Alternative Name(s)**

Institutos Nacionales de la Salud, US National Institutes of Health, NIH

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United States of America

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

01/07/2020

**Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

**IPD sharing plan summary**

Other