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The role of inflammation in the outcomes of retinopathy of prematurity

Submission date	Recruitment status	[ ] Prospectively registered
07/06/2020	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/08/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/08/2020	Eye Diseases	[ ] 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?
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Contact information

Type(s)
Public

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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 particpiants 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 ≤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
Zafer Saglik Kulliyesi
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