

# Using artificial intelligence to help detect abnormal blood vessels in the eye

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<b>Last Edited</b> 06/10/2025	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study is looking at how artificial intelligence (AI) can help doctors diagnose a serious eye condition called retinopathy of prematurity (ROP) in premature babies in Nepal. ROP is a leading cause of childhood blindness, and as more premature babies survive due to better medical care, the risk of ROP is increasing. The study will test whether a computer program called i-ROP can accurately detect signs of ROP by looking at eye images, and compare its results with those of human eye specialists. It will also explore whether AI can help predict which babies are most at risk and test a low-cost smartphone tool for eye screening.

### Who can participate?

Premature babies born before 34 weeks of pregnancy or weighing less than 2000 grams (2kg) can take part in the study. A total of 584 babies will be enrolled over three years.

### What does the study involve?

Babies in the study will have regular eye checks using a special camera that takes pictures of the back of the eye. These images will be looked at by both eye doctors and the AI system. If there are any differences in diagnosis, a senior expert will make the final decision. Babies will be followed until their eye blood vessels have fully developed or until they reach 42 weeks of age.

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

The main benefit is early detection of ROP, which can help prevent blindness. The study may also lead to better, more affordable screening tools in the future. Risks are minimal and mainly related to the eye imaging process, which is safe but may cause temporary discomfort.

### Where is the study run from?

The study is being carried out at three hospitals in Nepal: Tribhuvan University Teaching Hospital, Tilganga Institute of Ophthalmology, and Kathmandu Medical College. It is led by Nepal Netra Jyoti Sangh in collaboration with the London School of Hygiene and Tropical Medicine (UK).

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

April 2025 to April 2029

Who is funding the study?  
Velux Stiftung (Switzerland)

Who is the main contact?  
ranjan\_shah@nnjs.org.np

## Contact information

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

Evaluating a deep learning algorithm in the diagnosis of retinopathy of prematurity (ROP) in Nepal and a prediction model for development of ROP

### Acronym

AI-ROP

### Study objectives

To evaluate a deep learning algorithm in the diagnosis of retinopathy of prematurity (ROP)  
Specific objectives:

1. To determine diagnostic accuracy of deep learning algorithm for the diagnosis of different severities of ROP as compared to the reference standard diagnosis (RSD)
2. To determine the diagnostic accuracy of the deep learning algorithm for the diagnosis of TR\_ROP and RW\_ROP as by using vascular severity score (VSS)
3. To develop a prediction model for ROP based on clinical characteristics from the cohort of preterm newborn screened for ROP.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 19/11/2024, Ethical Review Board of Nepal Health Research Council (Ramshah Path, Kathmandu, 44600, Nepal; +977 1 5354220, +9771 5327460; nhrc@nhrc.gov.np), ref: 1090

### Study design

Prospective observational cohort study

### Primary study design

Observational

### Study type(s)

Screening, Treatment

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

## Diagnosis of retinopathy of prematurity

### Interventions

Neonates meeting the inclusion criteria were recruited from four study centres (with TUTH and BPKLCOS, both under the Institute of Medicine [IOM], considered as a single centre). Informed consent was obtained from the parents or guardians prior to enrolment. Relevant details, including risk factors, birth weight, and gestational age, were recorded in the case record form (CRF). Following adequate pupillary dilatation, fundus photographs were captured using the Forus camera and uploaded for assessment. The respective team leaders at each study centre reviewed the images and documented the diagnosis of retinopathy of prematurity (ROP), including stage and grade. Based on the diagnosis, a decision was made regarding the need for treatment or observation.

Infants advised observation were followed every two weeks until complete maturation of retinal vascularisation, which typically occurs at around 42 weeks of gestational age. Those requiring treatment underwent longer follow-up until full vascularisation of the retina was achieved.

### Intervention Type

Drug

### Phase

Not Applicable

### Drug/device/biological/vaccine name(s)

Forus trinetra camera for fundal imaging

### Primary outcome(s)

1. Sensitivity of ROP detection is measured using comparison between AI model output and Reference Standard Diagnosis (RSD) from fundus images captured with the Forus camera at each imaging timepoint during two-weekly follow-up until 42 weeks gestational age or complete retinal vascularisation
2. Specificity of ROP detection is measured using comparison between AI model output and Reference Standard Diagnosis (RSD) from fundus images captured with the Forus camera at each imaging timepoint during two-weekly follow-up until 42 weeks gestational age or complete retinal vascularisation

### Key secondary outcome(s)

There are no secondary outcome measures

### Completion date

30/04/2029

## Eligibility

### Key inclusion criteria

Gestational age 34-36 weeks in children with risk factors such as need of respiratory support, oxygen therapy for more than 6h, sepsis, episodes of apnea and need of blood transfusion, exchange transfusion or unstable clinical course as determined by pediatrician

### Participant type(s)

Patient

**Healthy volunteers allowed**

No

**Age group**

Neonate

**Lower age limit**

20 days

**Upper age limit**

34 weeks

**Sex**

All

**Key exclusion criteria**

1. Any premature babies already treated for ROP
2. Poor image quality of any of images

**Date of first enrolment**

01/04/2025

**Date of final enrolment**

30/09/2028

**Locations****Countries of recruitment**

Nepal

**Study participating centre**

**Tilganga Institute of Ophthalmology**

Gaushal

Kathamndu

Nepal

44600

**Study participating centre**

**Institute of Medicine/Tribhuvan University Teaching Hospital/BP Koirala Lions Center for Ophthalmic Studies**

Maharajganj

Kathmandu

Nepal

44600

**Study participating centre**  
**Kathmandu Medical College**  
Sinamangal  
Kathmandu  
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**Study participating centre**  
**Nepal Netra Jyoti Sangh**  
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## **Sponsor information**

**Organisation**  
International Centre for Eye Health (ICEH)

## **Funder(s)**

**Funder type**  
Charity

**Funder Name**  
Velux Stiftung

**Alternative Name(s)**  
Velux Foundation

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Trusts, charities, foundations (both public and private)

**Location**  
Switzerland

## **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

[ranjan\\_shah@nnjs.org.np](mailto:ranjan_shah@nnjs.org.np)

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			29/09/2025	No	Yes
<a href="#">Protocol file</a>	version 2.0	24/11/2024	29/09/2025	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes