ISRCTN62477762 https://doi.org/10.1186/ISRCTN62477762

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

Submission date 03/09/2025	**Recruitment status** Recruiting	[_] Prospectively registered [X] Protocol
Registration date 02/11/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 06/10/2025	**Condition category** Neonatal Diseases	[_] Individual participant data [X] 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?
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Contact information

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Principal investigator

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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
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44600

Study participating centre
Nepal Netra Jyoti Sangh
Tripureshwor
Kathmandu
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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.
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IPD sharing plan summary

Available on request

Study outputs

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