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Anaesthesia for laser treatment of retinal disease in premature infants

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Registration date 15/04/2026	**Overall study status** Ongoing	
Last Edited 13/04/2026	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

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Additional identifiers

Study information

Scientific Title
Anaesthesia for laser treatment of retinopathy of the premature

Acronym
ROP ANES -25 NOV

Study objectives
The care of premature infants with retinopathy of prematurity (ROP) is multidisciplinary and complex. Due to their prematurity and comorbidities, these patients have a high perioperative risk. Studies into the best anaesthetic care for this group are limited, among other reasons, due to small patient numbers and the diversity of care globally. It is currently unclear what the best form of airway management, general anesthesia and analgesia is for premature neonates undergoing laser treatment for ROP.

As of 01/07/2023, the standard of care during laser treatment of ROP in this tertiary referral center has become spontaneous or mechanical ventilation through a supraglottic airway device (laryngeal mask airway) with analgesia by continuous infusion of remifentanil and anaesthesia with continuous infusion of propofol (postmenstrual age (PMA) >37 weeks) or midazolam (PMA <37 weeks).

The primary study objective is to evaluate the current anaesthesiological practice during laser procedures for retinopathy of the premature (ROP).

The secondary study objective is to compare anaesthesiological outcomes between this current and the previous (historical) anaesthesiological practice.

Ethics approval required
Ethics approval not required

Ethics approval(s)

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Retinopathy of prematurity (ROP)

Interventions

The primary objective will be achieved by analyzing the primary and secondary anaesthesiological and opthalmological endpoints. The achievement of the secondary objective will be dependent on the final group size of the historical cohort.

Primary endpoint:
Respiratory deterioration, defined as an increase of ventilatory support in the first 24 hours postoperatively, compared to the preoperative ventilatory support requirement.

Secondary endpoints:
Perioperative, anesthesiological:
1. Number of airway management attempts
2. Saturation drop <85% SpO_2
3. Thoracic rigidity
4. Laryngeal spasm
5. Aspiration
6. Bradycardia <100 bpm
7. Tachycardia (>160-180 depending on post-menstrual age [PMA])
8. Hypotension (mean arterial blood pressure < PMA) with/without treatment
9. Hypertension (mean arterial pressure [MAP] >95th percentile based on PMA)
10. Preemptive medication
11. Rescue medication: yes/no

Perioperative, ophthalmological:
1. Surgical working conditions perioperatively (visualization good/moderate/poor)
2. Total operating time and per eye in minutes
3. Number of coagulates
4. Postoperative complications (<8 weeks): yes/no
5. Progression of ROP to stage 4 or 5: yes/no

Postoperative within 24 hours after the procedure:
1. Persistent respiratory/circulatory distress requiring conservative management: yes/no
2. Apnea: cessation of breathing >20 seconds or less with concomitant bradycardia (<60 bpm) /desaturation (<85% SpO_2), or an increase in episodes of apnea in the case of pre-existing apnea
3. Caffeine requirement postoperative: yes/no
4. Hypothermia <36.5 °C immediately after end of anesthesia/arrival from OR to the NICU: yes/no
5. Comfort score

Number of study participants:
A total of approximately 150 patients will be included, in order to obtain 100 patients that received anaesthesiological treatment as defined by current local protocol. The amount of patients in the historical cohort will add to these 100 patients.

Sample size:
For sample size calculations based on the precision of the (95%) confidence interval, the most recent literature regarding the rate of postoperative mechanical respiratory support with the use of sedation vs. general anesthesia (Ulgey, 2015) and laryngeal mask vs. intubation (Trinh, 2025) in laser interventions for ROP was used. With the inclusion of 100 patients in the current-practice cohort and approximately 50 patients in the historical cohort, an estimated probability of respiratory deterioration requiring mechanical ventilation of 7% (6-8%) in the current-practice cohort and 55% (37-74%) in the historical cohort is assumed. With these assumptions, the 95%

confidence interval around the difference in proportions will have a width of approximately 28% (CI: 0.33-0.61%), which offers sufficient precision to demonstrate a statistically relevant difference, since the interval does not contain the zero.

Follow-up:
Follow-up will be limited due to discharge to the referring center for a portion of the patients, usually after one day postoperatively. If an ophthalmological complication or progression has occurred after treatment, this will be reported by the referrers and the patient referred back. If this is not the case, it can be assumed that the ROP has stabilized. The number of patients lost to follow-up will be described. Relevant clinical observations not directly related to the laser treatment will be mentioned.

Statistical analysis:
Data will be analyzed using SPSS. Because tests for the normality of a distribution lack the power to detect clear deviations from normality in small sample sizes and pick up irrelevant deviations from normality in large sample sizes, the data will be described using histograms /density plots. If there are clear deviations from normality (e.g., clear skewness, more than one central peak), the data will be described using median and p25, p75; otherwise, using mean and SD. In the case of skewness, it will be determined whether this can be corrected after a log transformation (or square root transformation), and if so, analyses will be performed at that scale (and back-transformed for interpretation). Given the relatively large number of outcome parameters and the observational nature of the study, the focus will be on estimating (differences in) means and proportions with their 95% CI. Where possible, the distributions of the historical and current cohorts will be displayed side-by-side (both histograms/density plots in one figure, bar charts of both distributions in one figure). P-values will be calculated from t-tests and ANOVA (if three cohorts can be formed); for non-parametric outcomes, the Chi-square test will be used, and if sufficient data are available for comparison between more than three different cohorts, the Kruskal-Wallis test. To examine correlations, the Pearson correlation coefficient will be used for parametric outcomes, and Spearman's rank correlation coefficient or Kendall's tau for non-parametric outcomes. Given the number of outcomes, no correction will be made for multiple tests; instead, the overall picture across all outcomes will guide the interpretation of the study. Since we know that midazolam is used instead of propofol in the current anaesthetic protocol for neonates <37 weeks PMA, we will correct for this, unless drug use is entirely related to age.

Intervention Type
Drug/Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Remifentanil, morphine, fentanyl, esketamine, midazolam, propofol, sevoflurane, laryngeal mask airway, endotrachial tube

Primary outcome(s)
1. Respiratory deterioration measured using data reported by clinicians on the increase of ventilatory support at (within) the first 24 h after laser treatment

Key secondary outcome(s))

Completion date
01/01/2029

Eligibility

Key inclusion criteria
1. Have had laser treatment for ROP in Radboudumc/Amalia Children's Hospital
2. Age <1 year at time of surgery

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
1 days

Upper age limit
1 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Registered statement by parents/caregivers of no agreement to participation in scientific research
2. Multiple surgeries that are not eye laser treatments during one session of anaesthesia

Date of first enrolment
15/04/2026

Date of final enrolment
12/03/2027

Locations

Countries of recruitment
Netherlands

Sponsor information

Organisation
Radboud University Medical Center

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type

Funder Name
Radboud Universitair Medisch Centrum

Alternative Name(s)
Radboudumc, Radboud University Medical Center, Radboud University Nijmegen Medical Center, RUNMC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Radboud data repository: https://data.ru.nl/datastewardship.im@radboudumc.nl Andrea Frielink-Loing (Radboudumc)

IPD sharing plan summary
Stored in publicly available repository