

COVER PAGE:

Brief Title: ROP Check Database Premature Infant Outcomes

NCT Number: not yet assigned

Unique Protocol ID: ROPCHECK24

Study Protocol and Statistical Analysis Plan

This study has IRB review and does NOT require consent.

Investigator: Robert W. Arnold, MD

Observation trial of de-identified data from large ongoing US clinical dataset covering academic and private hospitals.

Data reviewed concerning those infants who progressed to threshold for therapy (Type 1) and what type of therapy delivered.

Statistics are typical descriptive statistics from database including median, interquartile range and percentages.

These are analyzed with Mann-Whitney, Kruskal-Wallis and Chi Square.

The workflow (encounter volume) for each infant is analyzed.

The AAP guideline ROP screening criteria are evaluated in light of other recent proposals and compared to the ROP Check® dataset.

“ROP Check® (NeoLight, LLC, Phoenix, Arizona) is a cloud-based electronic medical record (EMR) with built-in decision support used for ensuring ROP exams occur in a timely manner assisting neonatologists conform to complex screening guidelines, and for ophthalmologist tracking ROP staging exams and treatment. We use a de-identified data set of examination results from 28 hospitals which employed the software from 2010 through 2022. The acuity level of the neonatal intensive care units (NICUs) is as follows: four Level 4 NICUs, six Level 3B NICUs, twelve Level 3 NICUs, and six Level 2 NICUs and included both academic and non-academic centers. The American Academy of Pediatrics ROP guidelines recommend all infants less than 31 weeks gestational age (“a gestational age of 30 or less [completed weeks] (as defined by the neonatologist”) require

ROP staging exams¹. Surviving infants with birth gestational age of 21+6 weeks to 30+6 weeks are included in the analysis. IRB exemption (45 CFR § 46.104(d)(4),) was obtained for using the de-identified data set from WCG IRB on 3/4/24. The study complies with the Declaration of Helsinki and the Health Insurance Portability and Accountability Act (HIPAA). Hospitals initiated the use of the program at different years. The infant's race is diagnosed by the neonatologist was recorded by NICU clinical staff.

Patient demographic characteristic data, such as birthweight and gestational age, and details of numbers and timing of recorded encounters (either examinations or treatments) in ROP Check® are analyzed for non-normal distribution by Shapiro Wilk test before non-parametric analysis.

Recently proposed alterations to the AAP screening guidelines have been published but until now, not yet compared with a North American cohort of premature infants with substantial numbers of infants of Pacific races that are at high risk for treatment-warranted ROP²⁻⁵.”

Compared study cohorts							ROP Check® from 2010 to 2022									
Study	Years	patients	BW>	GA>	1st exam?	miss ?		missed ?	Avoid ?	Cohort	Treat	%Tx	Tx GA		%ROP	Pacific
E-ROP	2004-22	1257 of 6729	750	27	37 wk	1		4	2.0%	2975	32	1.1 %	33.6	41.6	80%	15%
First-ROP	2017-23	1125 of 2004	800	27	34 wk	0		4	8.6%	2917	29	1.0 %	33.6	41.6	80%	47%
Moir +	2003-22	6025 of 8364	1000	29	31-34 wk	0		4	3.1%	1543	4	0.3 %	36.1	37.9	90%	50%
SCREEN-ROP	2016-24	61 of 823	1200	30	31-34 wk	0		2	"7.6% "	625	2	0.3 %	37.5	37.7	94%	22%
TWO-ROP	2013-23	1095 of 3239	1500	30	38-9 wk	0		3	2.2%	989	3	0.3 %	37.5	37.9	91%	21%
ROP Check®										5058	387	7.7 %	29.1	47.7	59%	13%
"30+4"	2010-22	287 of 5058	any	30+4	31-34 wk	na		0	2.5%	287	0	0.0 %	na	na	93%	25%

ROP-if-P	2010-22	957 of 5058	140 0	30	31-34 wk	na	0	7.90%	957	0	0.0 %	na	na	92%	0%
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References:

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