

# Multicenter Trial of Cryotherapy for Retinopathy of Prematurity (CRYO-ROP)



## Objective

To determine changes in clinical outcomes following cryotherapy or a non-treatment control in the management of retinopathy of prematurity (ROP).

## Methods

**Design:** Randomized Controlled Trial

**Sample Size:** 291 infants with ROP

**Treatment Groups:**

- Bilateral ROP patients received cryotherapy in one eye only
- Unilateral ROP patients either received cryotherapy in that eye or received no treatment

**Outcome Measures:**

- Anatomic outcomes based on fundus photography grading
- Functional outcomes based on visual acuity testing (different based on age)

## Results

**Point 1:** There were improvements in structural outcomes with treatment

- There was a 49.3% reduction in the unfavorable outcome rate at 3 months in the treated eyes vs the untreated eye (21.8% compared with 43.0%)
- There was a 45.8% reduction in the unfavorable outcome rate at 12 months in the treated vs untreated eye (25.7% compared to 47.4%)

**Point 2:** There were similar improvements in functional outcomes with treatment, though not a significant improvement in highly functional vision (20/40 or better)

- There was a reduction in the unfavorable outcome rate at 10 years (44.4% in treated vs 62.1% in controls,  $P < 0.001$ )
- At 10 years, the percentage of eyes with VA better than 20/40 vision was similar in control and treated eyes (23.7% to 25.2%,  $P = 0.63$ )
- It was felt that anatomic success may have overestimated the efficacy of treatment compared to long-term functional success

**Point 3:** Treated eyes had lower rates of retinal detachment

- At 5.5 years, 22.1% of treated eyes had total retinal detachments compared to 38.6% of control eyes
- At 10 years, treated eyes were stable at 22%, whereas untreated eyes were up to 41.4%

**TLDR: Cryotherapy ablative treatment led to significantly improved anatomic outcomes and mostly improved functional outcomes for patients with threshold ROP**