



Retinopathy Of Prematurity Clinical Research Study

A clinical trial for retinopathy of prematurity (ROP) is currently enrolling and it may be of interest to you and the patients with whom you work.

ROP, which can develop in premature infants, is one of the most common causes of vision loss in childhood and can lead to lifelong vision impairment and blindness. Babies born very prematurely lose access to important intrauterine factors, such as IGF-1 (insulin-like growth factor-1), that help with fetal development. Deprivation of IGF-1 can lead to ROP and other complications. Although there are treatments such as cryotherapy and laser therapy that may reduce the incidence of blindness once ROP occurs, preventative therapies for ROP are needed.

The purpose of the ROPP study, ROPP-2008-01, is to evaluate the safety and efficacy of the use of mecaseimerin rinfabate (rhIGF-1/rhIGFBP-3) for preventing the development of ROP in very prematurely born infants, as compared to an untreated control group receiving the standard of care.

Parents at higher risk for premature delivery, including mothers expecting multiples, mothers on bed rest, and mothers who have had previous premature deliveries may be interested in connecting with a neonatologist and asking questions about the study and what is involved prior to delivery. Parents can also consent for the study prior to delivery, which may be beneficial due to the short 24-hour window for enrollment after birth.

In order to qualify for this study, infants must be between the gestational age (GA) of 23 weeks and 27 weeks + 6 days. Other eligibility criteria will be assessed at birth, including body weight, blood glucose level, and any other significant conditions.

If you or your colleagues care for any patients that may be interested in learning more about this potentially preventative therapy, please consider referring them to the ROPP-2008-01 study.

Interested in learning more about the ROP study?

Would you or your colleagues be interested in referring potential patient parents to the study?

You can read more about the study, find study locations near you, and request to be contacted by a study doctor at www.ROPResearch.com.

Parents can read more about the study on our patient-friendly website, www.ROPClinicalTrial.com.

You can also contact Adina Tocoian, MD, PhD, Shire EU Clinical Development Lead, at +41 41 2884369 or atocoian@shire.com or Alexandra Mangili, MD, MPH, US Clinical Development Lead, at 781-482-9049 or amangili0@shire.com.