

PRESERVE-1 Phase 3 Clinical Study

Overview

PRESERVE-1 (Prospective Randomized Evaluation of the Safety and Efficacy of Recombinant Antithrombin in Very Preterm Pre-Eclampsia) is a Phase 3 clinical study of ATryn (antithrombin [Recombinant]), for the treatment of early-onset preeclampsia defined as preeclampsia that occurs between weeks 23 and 30 of pregnancy.

Objective

The objective of the PRESERVE-1 study is to assess whether ATryn:

- Safely prolongs pregnancy by delaying delivery
- Decreases neonatal rates of death and disability

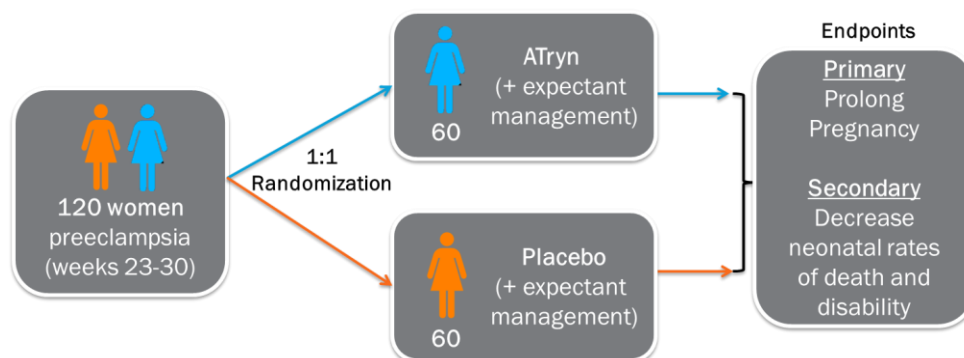
Inclusion Criteria

- At least 16 years of age or older
- Singleton pregnancy
- 23 to 30 weeks pregnant with a recent diagnosis of preeclampsia or superimposed preeclampsia
- Eligible for expectant management



Design

PRESERVE-1 is a randomized, double-blind, placebo controlled trial to assess the safety, efficacy and pharmacokinetics (PK) of ATryn in patients who are expectantly managed for early onset preeclampsia.



Eligible patient who meet inclusion/exclusion criteria will be randomized in a 1:1 ratio to receive a continuous infusion of either ATryn or placebo. Patients will continue on the study drug until maternal and/or fetal indications for delivery necessitate cessation of expectant management or until 34 weeks of gestation.

Efficacy will be assessed by comparing the difference in gestational age from the time of randomization into the trial until delivery of the baby in women given ATryn to those given placebo. The effect of ATryn on neonatal clinical outcomes will also be assessed.

Enrollment

Up to 120 pregnant women diagnosed with early onset preeclampsia will be enrolled across 25 to 30 study sites in North America. For more information, visit www.PRESERVE-1.org.

References

1. The Preeclampsia Foundation. FAQ. Available at: <http://www.preeclampsia.org/health-information/faqs>. Last updated December 2013. Accessed on February 12, 2014.
2. rEVO Biologics, Clinical Trial protocol : RB AT PPE 01-13