

New clinical trial at SLU treats preeclampsia in second-trimester pregnancies

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Saint Louis University is participating in a Phase III clinical trial for a drug to treat early-onset preeclampsia in pregnant women that could increase the length of pregnancy, resulting in improved fetal outcomes and reduced infant mortality.

ATryn, or antithrombin recombinant, is being studied to treat [preeclampsia](#) in pregnant women during the second trimester of [pregnancy](#) as part of the PRESERVE-1 trial.

"We are trying to prolong pregnancy in the second trimester," said Erol Amon, M.D., J.D., a SLUCare Physician Group obstetrician and a professor of maternal-fetal medicine at Saint Louis University School of Medicine. "We are looking to enroll women who are in their 23rd week to 30th week of pregnancy."

The randomized, double-blind, placebo-controlled trial will assess whether ATryn, produced by rEVO Biologics Inc., prolongs pregnancy in mothers with early-onset preeclampsia and reduces the high rates of perinatal mortality and disability. SLU enrolled its first patient in the trial this summer at SSM St. Mary's Hospital - St. Louis.

Preeclampsia occurs during pregnancy, affecting both the mother and the unborn baby. According to the Preeclampsia Foundation, preeclampsia occurs in 5 to 8 percent of all pregnancies. An expectant mother can experience swelling, sudden weight gain, headaches and changes in vision.

The drug is offered to expectant mothers in their second trimester experiencing preeclampsia once they are stabilized. Amon said previous trials have shown that Antithrombin extends pregnancy by about a week.

"Antithrombin has been shown to work in multi-center trials in Japan and Italy," Amon said. "We are hoping to reproduce and improve on those times in this study."

Amon noted that the American population of [pregnant women](#) tend to have more serious hypertensive disorders than those in Japan and Italy. "There are many reasons - race, body weight, the young age of the mother," Amon said.

"I am treating two patients - the mother and the child," Amon said. "If we were only concerned about the health of the mother, then we would deliver immediately. However, keeping the fetus in the womb increases the opportunity for lung maturity and improves outcomes for the child. We are concerned with both maternal and fetal health."

There are several theories as to why women develop preeclampsia, Amon said, but no specific cause has been clearly identified. Women who are obese, suffer from diabetes, those who suffer from hypertensive disorders and teenage mothers all have higher incidences of preeclampsia. Women who develop preeclampsia also are more likely to have it again in a subsequent pregnancy.

"There are also some studies that family history may play a role," he said.

Amon said previous studies on ATryn have shown it to be well-tolerated by patients with no adverse outcomes.

"This could be another needed advancement to prolong pregnancy for

patients with preeclampsia," Amon said. "As a high-risk pregnancy center, we receive preeclampsia patients from all over the region.

Our physicians, nurses and pharmacy staff are all superb. I truly believe that this is the best place in the bi-state area for women to be during their pregnancy."

Provided by Saint Louis University

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