

Study proves potential for reducing pre-term birth by treating fetus as patient

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The results of a study by researchers at the University of Texas Medical Branch may pave the way for a new medicine delivery system that could reduce the incidence of pre-term labor and premature birth by allowing physicians to treat the 'fetus as the patient'. The study has been published in *Science Advances*.

It has long been suspected that pre-term labor is triggered by inflammation caused by a sick [fetus](#). A new study by scientists at UTMB has proved the hypothesis by studying several important assumptions about the relationship between the health of a mother and her unborn child.

According to Dr. Ramkumar Menon, a Professor in UTMB's Department of Obstetrics and Gynecology and Cell Biology, his team worked with ILIAS Biologics, Inc., a South Korean biotechnology company, to test their bioengineered exosomes as a delivery system for anti-inflammatory medicine directly to the fetus.

"Exosomes are natural nanoparticles or vesicles in our bodies, and we have trillions of them circulating through us at all times. By packaging the medicine

inside a bioengineered [exosome](#) and injecting it into the mother intravenously, the exosomes travel through the blood system, cross the placental barrier and arrive in the fetus, where they deliver the medicine," explains Dr. Menon.

In laboratory tests with mice, there were several steps prior to testing the [drug delivery](#). First, Menon said it was important to prove that [fetal cells](#), specifically immune cells, actually migrated through the mother's body to her uterine tissues as well as to her, which can cause inflammation, the leading cause of pre-term labor.

To prove migration of cells, female mice were mated with male mice who had been genetically engineered with a red fluorescent dye called tdtomato. The dye causes cells in the male to turn red, so once mating has occurred, cells in the developing fetus also turn red and can easily be tracked as they migrate through the mother. This model was developed by Dr. Sheller-Miller, a post-doctoral fellow in the Menon lab who is also the first author of this report. Development of this model that determined fetal immune [cells](#) reaching maternal tissues was also a turning point in this research.

Once scientists had proof of cell migration, they next used the mouse model to determine if bioengineered exosomes could deliver a special anti-inflammatory medicine, an inhibitor of NF-kB, called super repressor (SR) IκB from the mother's bloodstream to the fetus.

The exosomes were created using an innovative approach developed by ILIAS Biologics, Inc. called EXPLOR, or Exosomes engineering for Protein Loading via Optically Reversible protein to protein interaction. The study proved that the exosomes effectively delivered medicine to the fetus, slowed the migration of fetal [immune cells](#), and delayed pre-term labor.

In addition, the study found that:

- * Sustained effects/delays in labor required repeated dosing
- * Prolongation of gestation improved pup viability
- * Mouse models provided valuable information to help understand the mechanisms often seen in humans
- * Future studies, including [human clinical trials](#) are needed to confirm laboratory results

"Pre-term birth rates have not reduced in the past few decades, and this technology (the bioengineered exosomes) could lead the way to other treatments for the delivery of drugs to treat the underlying cause of inflammation in a fetus," said Dr. Menon. This technology can also be used to package other drugs in exosomes to treat other adverse pregnancy complications.

This study result is the second proof of concept that suggests significant anti-inflammatory effects of the same exosomes from ILIAS Biologics. In April 2020, the researchers at Korea Advanced Institute of Science and Technology (KAIST) and the ILIAS team published the same exosomes' substantial efficacy in the septic mouse model in *Science Advances*.

More information: Samantha Sheller-Miller et al, Exosomal delivery of NF- κ B inhibitor delays LPS-induced preterm birth and modulates fetal immune cell profile in mouse models, *Science Advances* (2021). [DOI: 10.1126/sciadv.abd3865](https://doi.org/10.1126/sciadv.abd3865)

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