

Common blood thinner for pregnant women proven ineffective

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It's a daily injection to the belly for pregnant women at risk of developing blood clots and it's ineffective, according to a clinical trial led by researchers at The Ottawa Hospital and published today by the prestigious medical journal *The Lancet*.

As many as one in 10 pregnant women have a tendency to develop [blood clots](#) in their veins, a condition called thrombophilia. For two decades these women have often been prescribed the anticoagulant low molecular weight heparin (LMWH) to prevent pregnancy complications caused by placental blood clots. This treatment requires women to give themselves daily injections—a painful and demoralizing process that requires women to poke their abdomen with hundreds of needles over the course of their pregnancy.

Now, a randomized clinical trial led by Dr. Marc Rodger, a senior scientist at the Ottawa Hospital Research Institute who heads up the Thrombosis Program of The Ottawa Hospital, provides conclusive evidence that the commonly prescribed LMWH anticoagulant has no positive benefits for the mother or child. In fact, Dr. Rodger's study shows that LMWH treatments could actually cause pregnant women some minor harm by increasing bleeding, increasing their rates of induced labour and reducing their access to anesthesia during childbirth.

"These results mean that many women around the world can save themselves a lot of unnecessary pain during pregnancy," says Dr. Rodger, who is also a professor in the Faculty of Medicine at the

University of Ottawa. "Using low molecular weight heparin unnecessarily medicalizes a woman's pregnancy and is costly."

Since the 1990s, using LMWH to treat pregnant women with a tendency to develop blood clots became commonplace, despite the fact that a large, multi-site randomized clinical trial had never been conducted to prove its effectiveness. Low molecular weight heparin is also prescribed by many physicians worldwide to women, with and without thrombophilia, to prevent placenta blood clots that may lead to pregnancy loss, as well as preeclampsia (high blood pressure), placental abruption (heavy bleeding) and intra-uterine growth restrictions (low birth weight babies). The anticoagulant LMWH is also prescribed to prevent deep vein thrombosis (leg vein blood clots) and pulmonary embolisms (lung blood clots).

"While I wish we could have shown that LMWH prevents complications, we actually proved it doesn't help," adds Dr. Rodger. "However, I'm very glad that we can now spare these women all those unnecessary needles."

Allison McIntosh, a 34-year-old lawyer with the Department of Justice in Ottawa, knows the pain and dejection that people feel who pin their hopes of carrying a baby to term on the LMWH injections. After twice miscarrying, Ms. McIntosh was prescribed LMWH during her third pregnancy. She spent two-and-a-half months giving herself a needle every day only to find out the treatment didn't work when she miscarried for a third time.

"It was difficult after realizing that the injections didn't work," says Ms. McIntosh. "I thought that I was doing something to make a difference by giving myself the injections. I kind of lost hope after that experience."

Now pregnant for a fourth time, Ms. McIntosh says that she and her husband Jeremy Gaudet, decided to forgo LMWH or any other

injections this time around. Furthermore, she says that she is not surprised to hear that LMWH has been disproven as a means of preventing blood clots in pregnant women.

"I feel sad for other people who are going through that process," says Ms. McIntosh, who is now six months along in her latest pregnancy. "It can be disillusioning for people if those injections are their only hope."

Amy Mills, a 35-year-old mother of two young children, agrees with Ms. McIntosh and is relieved to hear that LMWH treatments have been disproven. Ms. Mills, who lives in Bancroft, Ontario, participated in Dr. Rodger's clinical trial after it was discovered that she is prone to developing blood clots. Prescribed LMWH by her doctor, Ms. Mills gave herself more than 400 needles full of the anticoagulant medication during the course of her pregnancy – often two needles a day. The process resulted in severe bruising and pain, says Ms. Mills, who works as a manager at McCaskie TV & Stereo in Bancroft.

"It hurt each and every time I injected myself," says Ms. Mills of the experience. "Most women are proud to show their pregnancy belly, but not me. There was so much bruising I had to keep covered up."

Today, Ms. Mills and her carpenter husband Jeff are the proud parents of seven-year-old Mikayla and five-year-old Joshua. Ms. Mills says she is glad that she participated in Dr. Rodger's study as it means other women won't have to go through what she endured. She adds that to prevent the development of blood clots during her pregnancy with second child Joshua, she merely took Baby Aspirin each day.

Dr. Rodger's clinical trial took 12 years to complete and involved 292 women at 36 centres in five countries. The study's results were published online today and will appear in a future print issue of *The Lancet*, one of the world's oldest and most prestigious medical journals. It is also the

subject of a Comment published online today.

"Dr. Rodger's findings will benefit many women in many countries who will be spared from hundreds of unnecessary and painful injections. They also underscore the importance of conducting rigorous, well-designed clinical trials, something we pride ourselves on at the Ottawa Hospital Research Institute," says Dr. Duncan Stewart, chief executive officer and scientific director of the Ottawa Hospital Research Institute, vice-president of research at The Ottawa Hospital and professor of medicine at the University of Ottawa.

Dr. Rodger says he hopes that doctors will stop prescribing LMWH to pregnant women with thrombophilia and/or with previous pregnancy complications when it isn't warranted. He also hopes the results of his study will cause some sober second thought in the medical community and bolster the use of evidence-based treatments.

"These findings allow us to move on, to pursue other, potentially effective, methods for treating pregnant women with thrombophilia and/or complications from placenta blood clots," says Dr. Rodger.

There is still one type of thrombophilia (anti-phospholipid antibodies) for which blood thinners may be effective in preventing recurrent pregnancy loss. Also, some women are advised to take low-dose aspirin while pregnant to help prevent pregnancy complications. All women with thrombophilia need blood thinners to prevent blood clots after delivery. As noted in the paper, some women with prior severe [pregnancy complications](#) might still benefit from blood thinners, but this requires further rigorous study. However, in all cases, [pregnant women](#) experiencing any type of prior complication should consult their doctor about the right course of treatment.

Provided by Ottawa Hospital Research Institute

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