Infliximab (Remicade®)

This sheet talks about exposure to infliximab in a pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare provider.

What is infliximab?
Infliximab is a medication used to treat autoimmune diseases such as rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, Crohn’s disease, and ulcerative colitis. For more information, please see the MotherToBaby fact sheets on rheumatoid arthritis (https://mothertobaby.org/fact-sheets/rheumatoid-arthritis/), psoriasis and psoriatic arthritis https://mothertobaby.org/fact-sheets/psoriasis-and-pregnancy/) and ankylosing spondylitis (https://mothertobaby.org/fact-sheets/ankylosing-spondylitis/). Infliximab is called a tumor necrosis factor-alpha (TNF) inhibitor because it binds to and blocks TNF, a substance in the body that causes inflammation in the joints, spine, and skin. Infliximab is given as an intravenous (IV) infusion and is sold under the brand name Remicade®.

I take infliximab. Can it make it harder for me to become pregnant?
Studies have not been done to see if infliximab could make it harder for a woman to get pregnant.

I just found out that I am pregnant, should I stop taking infliximab?
It is recommended that you talk to your healthcare provider before you stop taking this medication. The benefits of taking infliximab and treating your autoimmune condition during pregnancy need to be compared with the possible risks of continuing the medication.

Can taking infliximab during pregnancy increase the chance for miscarriage?
Miscarriage can occur in any pregnancy. Having an autoimmune disease may increase the chance for miscarriage, which makes it hard to know if the medications used to treat these diseases can also cause miscarriage. While some small studies suggest a higher chance of miscarriage among women treated with infliximab early in pregnancy, other studies do not. A recent study looking at 495 women exposed to a TNF inhibitor early in pregnancy (almost one third of the women were taking infliximab) did not find an increased chance for miscarriage.

Does taking infliximab in the first trimester increase the chance for birth defects?
In every pregnancy, a woman starts out with a 3-5% chance of having a baby with a birth defect. This is called her background risk. Infliximab has not been well studied for use in pregnancy, but the available data does not suggest a higher chance for birth defects. There are studies with a total of 223 women and some case reports of women who took infliximab during pregnancy with no increased chance for birth defects or other problems.

A study published in 2009 looked at birth defects reported in mothers who used a TNF inhibitor during pregnancy. The authors suggested these medications could cause VACTERL association, a pattern of birth defects that includes vertebral (spine), anal, cardiac (heart), tracheal-esophageal (structures in the neck), renal (kidney), and limb (arms and legs) defects. However, this study had many problems including limited data, voluntary reporting, and misdiagnosis of VACTERL association. Therefore, it does not support the conclusion that TNF inhibitors cause an increased chance for a pattern of birth defects.

In summary, small studies looking at infliximab use during pregnancy have not shown an increased risk for birth defects. It is also reassuring that a large amount of infliximab is not thought to reach the developing baby during the first trimester.
**Could taking infliximab in the second or third trimester cause other pregnancy complications?**

Recent information suggests that large amounts of infliximab do not cross the placenta to reach the developing baby in the first trimester. (The placenta is a temporary organ that develops during pregnancy and works as the blood connection between you and your baby.) As pregnancies continue, more of the medication is able to cross the placenta. As the pregnancy continues, more infliximab is believed to cross the placenta and reach the developing baby. At this time, there have not been any reports showing increased risks to the baby when a mother takes infliximab in the second or third trimester. There are no official recommendations to either stop or continue the use of infliximab later in pregnancy. The decision to use this medication in the later part of pregnancy should be made with your healthcare provider, and be based on your condition and the severity of your symptoms.

**Does taking infliximab in pregnancy cause long-term problems in behavior or learning for the baby?**

At this time, there are no studies on the possible long-term effects of infliximab on a baby.

**Can my baby receive live vaccines before 6 months of age if I take infliximab later in pregnancy?**

Most vaccines given in the first 6 months of life are inactivated or noninfectious and can be given to a baby even if the mother has used infliximab during pregnancy.

Rotavirus vaccine is the only live vaccine given to infants less than 6 months of age in the United States. Live vaccines usually contain a weaker (attenuated) form of the virus or bacteria and carry a small chance of infection. Live vaccines are usually not given to adults using TNF inhibitors like infliximab. This is because there is a concern that TNF inhibitors cause immunosuppression (decreased immunity) and therefore increase the chance of infection from the live vaccine.

If a baby is exposed to infliximab during pregnancy, they might still have the drug in their blood after birth. A healthcare provider may want to check the baby’s blood for infliximab before giving a live vaccine. If the medication is still in the baby’s blood, the healthcare provider can discuss the risks and benefits of giving a live vaccine to your baby. There is a single report of a woman treated with infliximab during pregnancy whose infant received a live bacille Calmette-Guerin (BCG) vaccine at 3 months of age. BCG is a vaccine that protects against tuberculosis (TB). The baby later died of a suspected BCG infection that spread throughout the body. However, it is not known if prenatal exposure to infliximab was at all related. The live BCG vaccine is not usually given in the U.S., but it is used in other countries where tuberculosis infections are common.

Another study looked into the effect of vaccinations in babies’ whose mothers used infliximab during pregnancy: no increased chance for infection was reported. Infants born to 19 of the women were on infliximab during pregnancy received the rotavirus vaccines. Of these, five infants had a fever and one had diarrhea. This study suggested rates of complications for the infants of mothers on infliximab compared to those not on infliximab were similar and no serious complications were reported.

**Can I breastfeed while taking infliximab?**

Reports of women who have breastfed while taking infliximab show that only a small amount of the medication enters breast milk. In addition to small levels in milk, infliximab is not well absorbed from the baby’s gut. This means that any of the medication that gets into breast milk, and is swallowed by the baby would be unlikely to enter their system. Studies on a small number of babies exposed to infliximab through breast milk that were followed up to a year did not report negative effects on development. It is possible that babies born prematurely (before 37 weeks of pregnancy), may absorb more of the medication through breast milk compared to full-term babies (born after 37 weeks of pregnancy) since their digestive systems are not fully developed. Recommendations for babies born prematurely might be different. Be sure to talk to your healthcare provider about all of your breastfeeding questions.

**If a man takes infliximab, could it affect his fertility (ability to get partner pregnant) or increase the chance of birth defects?**

One study of 10 men taking infliximab found changes in the shape and movement of their sperm. It is not known if these changes would affect fertility. Another small study of 11 men did not find evidence of fertility problems. There were also no birth defects or an increased rate of pregnancy complications reported in another 10 pregnancies when the father of the baby took infliximab before and during the pregnancy.

In general, exposures that fathers have are unlikely to increase risks to a pregnancy. For more information,
please see the MotherToBaby fact sheet Paternal Exposures and Pregnancy at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/.

MotherToBaby is currently conducting a study looking at autoimmune diseases in pregnancy. If you would like to learn more about this study, please call 1-877-311-8972 or visit https://mothertobaby.org/join-study/

Please click here for references.

August, 2019