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. This sheet talks about whether exposure to infliximab may increase the risk for birth defects over that background risk. This information should not take the place of medical care and advice from your health care provider.

What is infliximab?

Infliximab is a prescription medication used to treat some kinds of autoimmune diseases such as rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, Crohn’s disease, and ulcerative colitis. Infliximab is called a tumor necrosis factor (TNF) inhibitor because it binds 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. Infliximab is sold under the brand name Remicade®.

How long does infliximab stay in the body? Should I stop taking it before I try to get pregnant?

Individuals break down medicines at different rates. On average, it takes about seven weeks after the last infusion of infliximab for all of the medication to be cleared from the body. It’s recommended that you talk to your health care provider before you stop taking any 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 make it more difficult for me to become pregnant?

There are no reports linking infliximab to fertility problems. Infliximab is being studied to see if it may be used with other therapies to improve the success rates of certain fertility treatments in some women.

Can taking infliximab during my pregnancy cause birth defects?

Infliximab use during pregnancy is not well studied. In a survey sent to rheumatologists, the health care providers reported no increase in birth defects or miscarriage rates in 417 women exposed to infliximab or another TNF inhibitor during pregnancy. About one third of these women continued to take the medication throughout pregnancy. An analysis of cases reported to the infliximab safety database did not find an increased risk for birth defects or miscarriage in 78 pregnancies; most of these women took infliximab during the first trimester or within three months before conception. There have been other reports of babies that were exposed to infliximab during pregnancy and did not have a pattern of 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. VACTERL association is 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. Two or more defects in this pattern must be found for a baby to be diagnosed with VACTERL. Also, other syndromes or genetic disorders must be ruled out before a diagnosis of VACTERL can be made. However, due to the study design, limited data, and voluntary reporting, this review does not support the conclusion that TNF inhibitors cause an increased risk for a pattern of birth defects.

In summary, small studies looking at infliximab use during pregnancy have not shown an increased risk for a pattern of birth defects. It is also reassuring that a large amount of infliximab is not thought to reach the pregnancy during the first trimester. However, results from more studies are needed before we can be sure of the effects of infliximab on a pregnancy.
Can I take infliximab in the third trimester?

Because infliximab is a large protein, recent information suggests that a large amount of the medication is not able to cross the placenta and reach the developing baby until the second trimester. The placenta is a temporary organ that develops during pregnancy and works as the blood connection between you and your baby. As the pregnancy continues, more of the medication is able to cross the placenta.

Although more infliximab may cross the placenta during the third trimester than in the first trimester, there have not been any reports that have shown increased risks to the baby when a mom takes infliximab in the third trimester. At this time, there is very limited information looking at the use of infliximab in the third trimester. There are also no official recommendations regarding third trimester use. The decision to use infliximab in the later part of pregnancy should be made with your health care provider and may be based on your condition and the severity of your symptoms.

Can my baby receive live vaccines before one year of age if I take infliximab later in pregnancy?

Most vaccines given in the first 6 months of life are noninfectious and can be given to a baby even if infliximab is present in his/her blood. Noninfectious vaccines are not live vaccines, meaning a person cannot get the infection from the vaccine. Live vaccines always carry a small chance a person could contract the infection from the vaccine. However, live vaccines usually contain a milder form (attenuated) of the virus or bacteria than what you might be exposed to in the community. Types of live vaccines include measles-mumps-rubella (MMR), varicella (chicken pox) and rotavirus vaccine. The rotavirus vaccine is the only live vaccine given to infants less than one year of age in the United States. Rotavirus is one of the leading causes of vomiting and severe diarrhea in children. The rotavirus vaccine is a routine recommended immunization for infants in the US, and is the best way to protect infants against rotavirus disease.

There is a single report of a mother treated with infliximab during pregnancy whose infant received a live BCG vaccine at 3 months of age. The baby later died of a suspected BCG infection that spread throughout the body. However, it is not known if exposure to infliximab was at all related. The live BCG vaccine protects against tuberculosis and is not part of the recommended vaccinations for infants in the United States. This vaccine is not usually given in the US; it is used in other countries where tuberculosis infections are common.

While live vaccines are usually not given to those using TNF inhibitors like infliximab, vaccines protect babies from getting common infections that can sometimes cause serious or even life threatening illness in young children.

Always be sure to let your pediatrician know about any medications or exposures you had during pregnancy or breastfeeding, including treatment with TNF inhibitors. Your pediatrician can discuss the risks and benefits of live vaccines with you.

Can I take infliximab while breastfeeding?

Because infliximab is a very large protein, it is not likely that very much of the medication would be able to pass into breast milk. Also, infliximab is not well absorbed from the gut, so any of the medication that gets into breast milk would be unlikely to enter the baby’s system. It is possible that babies who were born before 37 weeks of pregnancy (premature) with digestive systems that are not fully developed may be able to absorb more of the medication through breast milk. Reports of women breastfeeding while taking infliximab showed only a small amount of the medication is passed into breast milk. Be sure to talk to your health care provider about all your choices for breastfeeding.

What if the father of the baby takes infliximab?

One study of ten men taking infliximab found changes in the movement and shape of their sperm. It is not known if these changes would affect fertility. Another small study on 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 ten 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 http://www.mothertobaby.org/files/paternal.pdf.
medications used to treat autoimmune diseases in pregnancy. If you are interested in taking part in this study, please call 1-877-311-8972.

References Available By Request