



Ocrelizumab (Ocrevus) and Pregnancy

Information on this page outlines the consensus opinion of the UK MS Pregnancy Register Steering Group and has been produced to help you in your discussions with your MS team about what you should do.

Ocrelizumab (Ocrevus)

- Ocrelizumab is a treatment for relapsing remitting MS and is given by drip every 6 months. In some people, particularly those who have been taking this medication for some time, these infusions may be given less frequently.
- Ocrelizumab remains in the body for approximately 20 weeks after each infusion, but its effect on the immune system lasts much longer than this.
- Ocrelizumab does not affect fertility in men or women.

Thinking about pregnancy (including pre-conception)

- These are some things to think about when considering pregnancy whilst you are being treated with ocrelizumab:
 - o In the UK it is recommended to use contraception for at least 12 months after the last infusion of ocrelizumab, not because it is known to be harmful, but that there has not been enough evidence to be certain that it is safe. In the US the recommendation is 6 months; this is because of the different ways that the regulators interpreted the available information when ocrelizumab was launched.
 - o Waiting only three months after your last infusion before trying to get pregnant may significantly reduce the chance of you relapsing whilst trying to get pregnant, and during and after pregnancy, whilst minimizing your baby's exposure to ocrelizumab.
 - o Even when conception occurs less than three months after the last infusion (or in the rare cases where ocrelizumab has had to be given during pregnancy) it hasn't been associated with birth defects, miscarriage, or prematurity. The information about this is increasing quickly, as more people are using ocrelizumab closer to pregnancy.
 - o Whilst the chances of having an MS relapse are lower during pregnancy, pregnancy alone may not be enough to prevent relapses in women with very active MS. Also, there is an increased risk of relapses in the first few months after your baby is born as pregnancy hormone levels return to normal.
 - o Whilst trying to get pregnant soon after your ocrelizumab infusion may sound risky, ocrelizumab does not cross the placenta during the first trimester. This means that if your last infusion was more than three months before you get pregnant (conceive), the baby will not be exposed to it. The longer-term effects on your immune system don't appear to cause harm to the baby as it develops in the womb.

What to do if you do not become pregnant after six months and your next infusion is due

- It can take longer than expected to get pregnant. If you have not become pregnant six months after your last ocrelizumab infusion, you can think about postponing your next infusion in discussion with your neurologist.
- However, if you haven't become pregnant 9-12 months after your last ocrelizumab infusion, you should seriously consider having another infusion. This is to try to avoid the risk of you relapsing.

During and after pregnancy

- If you find out you are pregnant whilst being treated with ocrelizumab, let your MS team know and they will usually pause your infusions until after your baby is born.
- It is safe to have MRI scans if needed whilst you are pregnant, but you should not have contrast injections unless this is specifically needed.
- Due to the increased risk of having a relapse after your baby is born, ocrelizumab should be restarted soon after birth.
- If you are breastfeeding, you should consider restarting ocrelizumab when your baby is at least one week old, as colostrum (early breastmilk) may contain more natalizumab than the milk that you produce after a week or so.
 - o Whilst ocrelizumab's license advises against breastfeeding due to a lack of safety data, the benefits of breastfeeding are likely to outweigh any risk to your baby.
 - o Studies have shown that ocrelizumab and similar drugs (known as antibodies) only pass into breast milk in tiny quantities and do not cause any changes in the baby's blood count, development, or other measures.

Advice on your baby's vaccinations if you have been treated with ocrelizumab less than three months prior to pregnancy, during pregnancy or whilst breastfeeding

- Most routine infant vaccinations are not affected, but rotavirus vaccine (which is given to your baby by mouth at 8 and 16 weeks) should be avoided. This is because this is a live vaccine. It cannot be given later than 20 weeks due to the risk of the vaccine to older babies.
- The other live vaccine that some people might be offered is BCG. This is not offered everywhere in the UK. If it is offered, it should be deferred by at least 6 months after the baby's last exposure.