

Use of Monoclonal antibodies against Coronavirus in pregnant women in Switzerland. 7.1.2022

Since mid-May 2021, treatment with the antibody combination Casirivimab/Imdevimab (REGN-COV2) from Regeneron/Roche has been possible in Switzerland. It can be administered to prevent progression from mild towards severe disease and it can also be used in some high-risk hospitalized patients (see reference document from OFSP/BAG and SSI)

REGN-COV2 is not effective against the Omicron variant. In this situation, another monoclonal antibody called Sotrovimab shall be used.

As the Omicron variant is the one mostly circulating now (>95%), Sotrovimab is the only type of monoclonal antibodies recommended unless the variant is determined in the laboratory.

Pregnant women

Pregnant women are at increased risk for severe COVID-19, potentially leading to ICU stay, intubation and maternal death, compared with non-pregnant women of the same age. In addition, the risk of adverse pregnancy outcome (preterm birth, preeclampsia, intra-uterine fetal death) is increased in pregnant women with severe COVID-19, compared with pregnant women without severe COVID-19.

Currently, there is a lack of in vivo data about the use (efficacy and safety) of Sotrovimab during pregnancy. The only available information according to Swissmedic is: "in a cross-reactive binding test using a protein array enriched with human embryo-fetal proteins, no off-target binding was found". In addition, the risk benefit ratio of this treatment may change if omicron is actually less virulent.

Hence, the question therefore arises whether pregnant women qualify for monoclonal antibodies treatment.

Criteria for administration of monoclonal antibodies in pregnancy

- Monoclonal antibodies can be offered in COVID-19 during pregnancy, after a detailed counseling about benefits and risks (please refer to guidelines from your hospitals and/or document from the SSI). Signing an informed consent form is not requested by the OFSP/BAG.
- Purpose of the treatment: avoiding progression to a severe COVID-19 with admission to the ICU (intensive care unit) and avoiding adverse neonatal outcome

Selection criteria of Sotrovimab:

The criteria are the same as outside pregnancy. Due to the lack of data, its use during the first trimester should be avoided.

- Mild or moderate infection*
- AND a duration of symptoms of ≤ 5 days
- **AND co-morbidities*** (risk for severe disease according to the OFSP/BAG list, dated December 23rd 2021)
- AND Gestational age > 12 weeks of gestation
- Not fully vaccinated status (exceptionally recommend to vaccinated patients for > 4 months who have no immune response, e.g. immunosuppressed, after serum Ab-titer determination)

A multidisciplinary discussion between obstetricians and ID specialists is recommended before administration.