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# New treatment for alloimmunisation in pregnancy

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FROM THE SPECIALTIES

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The author has completed the ICMJE form and declares the following conflicts of interest: She is a research assistant and principal investigator at a fetal medicine centre involved in the nipocalimab clinical trial. She has also attended a training meeting for researchers in the FREESIA-1 study discussed in the article. Travel and accommodation expenses were covered by the commissioning party, Janssen.

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## **The introduction of blood type screening followed by anti-D prophylaxis is a success story in perinatology. New treatment principles are now being developed for alloimmunisation in pregnancy.**

Haemolytic disease of the fetus and newborn was once a major contributor to perinatal morbidity and mortality. The treatment for fetal anaemia is intrauterine transfusion. Since the introduction of RHD genotyping of the fetus (using non-invasive prenatal testing) and antenatal prophylaxis for RhD-negative women in Norway in 2016, the number of intrauterine transfusions due to RhD alloimmunisation has decreased. In the period 2012–2016, there were 24 intrauterine transfusions in Norway each year, compared to 15 per year for this indication from 2022 to 2024 (Kjell Salvesen, personal communication). The total number of annual intrauterine transfusions is slightly higher as there are also other causes of fetal anaemia, such as parvovirus infections and Kell alloimmunisation [\(1\)](#).

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## **New treatment principles offer new hope**

A recent phase 2 study showed that a new drug, nipocalimab, can prevent severe haemolytic disease of the fetus [\(2\)](#). Nipocalimab is an anti-neonatal Fc receptor blocker that both shortens the half-life of IgG in maternal circulation

and inhibits transplacental IgG transfer. In combination, this reduces IgG alloantibody transfer to the fetus. The study offers hope for the effective treatment of alloimmunisation.

Another immunisation disorder in the fetus and newborn is fetal/neonatal alloimmune thrombocytopenia (FNAIT). The mother forms alloantibodies against the fetal platelets, resulting in thrombocytopenia in the fetus and newborn. In approximately 10 % of cases, this can cause severe brain haemorrhages in the fetus and newborn, which may lead to perinatal death or serious neurological sequelae. Unlike Rhesus alloimmunisation, there is no screening to identify the approximately 2 % of pregnant women with the platelet type that carries a risk of FNAIT, nor is there any prophylaxis. Current treatment involves weekly administration of intravenous immunoglobulin to the expectant mother. The benefit of treating pregnant women who have a known risk of FNAIT is controversial.

Four fetal medicine centres in Norway are currently participating in a randomised controlled trial in which women at risk of FNAIT are receiving either a placebo or nipocalimab (3). Two of the centres are also involved in a phase 2 study to evaluate an antibody-mediated prophylaxis to treat FNAIT (similar to the anti-D immunoglobulin prophylaxis for Rhesus alloimmunisation) (4).

If these new treatments prove to be safe and effective, they could mark a significant advancement in the prevention and treatment of several prenatal alloimmune disorders. Norway's participation in and contribution to these studies play a crucial role in this groundbreaking work.

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