Sistema Socio Sanitario
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AZIENDA SOCIO SANITARIA TERRITORIALE DEI SETTE LAGHI

S.C. Ginecologia e Ostericia

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Informed consent for routine administration of anti-D immunoprophylaxis in pregnancy

INTRODUCTION

Women who have a Rh negative group during pregnancy can develop an immune response (i.e. produce antibodies, called anti-D) against the red blood cells of the fetus, which the maternal body identifies as foreign because they are different from their own. This can only happen if the baby's father is Rh positive and the fetus is Rh positive. Maternal antibodies attack and destroy the red blood cells of the fetus; the possible consequence is anemia, known as haemolytic disease of the fetus, which in severe cases can lead to intrauterine death.

DEFINITION OF THE PROPOSED HEALTH TREATMENT

Anti-D immunoprophylaxis consists in the administration, by intramuscular injection, of 300 µg of human anti-D immunoglobulin to Rh negative women, in order to prevent the formation of maternal antibodies against the red blood cells of the fetus.

PURPOSE

Anti-D prophylaxis minimizes the risks associated with hemolytic disease of the fetus.

METHOD OF PERFORMANCE

In women with Rh negative anti-D prophylaxis must always be performed after so-called "sensitizing" events, e.g. all situations in which there is potentially contact between maternal and fetal blood (e.g. after the birth of a newborn) Rh positive, after an abortion, in case of uterine blood loss or abdominal trauma, after invasive maneuvers such as amniocentesis ...).
There are several studies documenting positive effects in carrying out routine anti-D prophylaxis, i.e. to all Rh negative women during pregnancy regardless of whether a "manifest" sensitizing event has occurred. In fact, it is believed that in the third trimester of pregnancy “silent”, unidentifiable sensitization may occur (generally due to small transplacental hemorragies).

POSSIBILITY and PROBABILITY OF RESULTS THAT CAN BE OBTAINED WITH THE TREATMENT

Almost all of the silent sensitizations have no consequences for the pregnancy in progress. However, once the mother is sensitized, the risk of subsequent Rh-positive offspring developing fetal hemolytic disease increases progressively. Therefore, a woman will have a clinical benefit from anti-D immunoprophylaxis only if she has a Rh-positive fetus, if she sensitizes in this pregnancy and if she has another Rh-positive child in the future. The immunoprophylaxis to 28-30to gestational week reduces the likelihood of immunization in future pregnancies from 9.5 in 1000 to 3.5 in 1000 (0.6% reduction).

REASONABLY FORESEEABLE RISKS

Prophylaxis has no side effects on the baby before and after birth. Rare cases of a mother's allergic reaction are documented. It should be remembered that anti-D immunoglobulins are blood products derived from human blood: there is therefore a remote risk (1 case every 10 trillion doses injected) of transmission of viral diseases (e.g. immunodeficiency, hepatitis, etc.).

Other exceptional outcomes or complications reported in the international literature are not excluded.

POSSIBLE POSSIBILITIES OF ALTERNATIVE HEALTH TREATMENTS

No alternative treatments to anti-D prophylaxis are reported.

CONSEQUENCES OF A REFUSAL TO PROPHYLAXIS

In the absence of routine anti-D prophylaxis, the probability of hemolytic anemia in Rh positive fetuses born to Rh negative mothers - including the mild forms which are the majority of cases - is 0.6% for the second child, 1.2% for the third and about 2% for the fourth.

INDICATIONS FOR THE PATIENT

· Before carrying out anti-D prophylaxis, it is necessary to perform the indirect Coombs test to detect the presence of anti-D antibodies in maternal blood. In case of positivity, prophylaxis is not performed.

· Immunoprophylaxis must be repeated within 72 hours of delivery if the infant is Rh positive or in the presence of sensitizing events more than 3 weeks after injection.

· The indirect Coombs test remains positive due to passive immunization after injection for 6-8 weeks; the persistence of a positive indirect Coombs test beyond 6-8 weeks should be carefully investigated

I have understood well what was explained to me by Dr..... ..... regarding

the risks associated with prophylaxis and those that could arise from not undergoing prophylaxis.

or I do not consent to the intramuscular injection of human anti-D immunoglobulin

or I agree to intramuscular injection of human anti-D immunoglobulin

Date:____/___/__

Doctor's name: _____

Patient Name:_____

Signature: _____

Signature: _____