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INFORMATIONAL FORM RELATED TO TREATMENT WITH ANTI-D IMMUNOGLOBULIN FOR THE PREVENTION OF HEMOLYTIC DISEASE OF THE NEWBORN

TREATMENT WITH ANTI-D IMMUNOGLOBULIN FOR THE PREVENTION OF HEMOLYTIC DISEASE OF THE NEWBORN

Dear Future Mother,

The form you have been given is a synthesis of the indications related to the treatment with anti-d immunoglobulin that was proposed to you, its method of execution, the risks involved, the benefits that could be obtained, and the consequences that may arise if you decide to refuse to undergo this treatment.

You will be subjected to this preventive treatment only after having freely and liberally given your consent. This is why you are asked to carefully read this document and, if you have any doubts, feel free to ask any member of the medical staff the questions you have so that you may fully comprehend its contents. The consent you give may always be revoked at any time you desire.

GENERAL INFORMATION

Pregnant women may develop an immune response (that is, produce antibodies and become immune) against the red blood cells of the fetus, which the maternal organism identifies as extraneous, since they are different than its own. The maternal antibodies attack and destroy the red blood cells of the fetus: a possible consequence is a certain type of anemia known as hemolytic disease of the newborn that, in more serious cases, may lead to an intrauterine death.

The most frequent case involved is the Rh factor, which occurs when the mother's blood type is **Rh Negative**, the father's blood type is Rh positive, and the fetus is Rh positive. In this case, the maternal organism may develop antibodies called anti-Rh(D). Generally, this does not occur during the first pregnancy but during the following ones, since the maternal organism, in most cases, develops these antibodies after the birth of the first child.

The immune response does not occur if the fetus is Rh negative and, therefore, compatible with that of the mother.

EXPLANATION OF THE TREATMENT PROPOSED

The **anti-D preventive treatment** consists in intramuscularly administering human anti-D immunoglobulin, which is a biological derivative, to Rh negative women, in order to prevent maternal antibodies from developing that would attack the red blood cells of the child.

The treatment involves a deep muscle injection.

OBJECTIVE

The **anti-D preventive treatment** allows for preventing or diminishing any possible risks for the newborn.

METHOD

The anti-D preventive treatment must be carried out within 72 hours from the birth of a Rh positive newborn. It should be administered for any condition that makes it possible for fetal red blood cells to pass to that of the mother (abortion, abnormal uterine bleeding, amniocentesis, chorionic villus sampling, cord blood testing, or other obstetric maneuvers).

Numerous studies have today demonstrated positive effects after routine anti-D preventive treatments given to **all Rh negative women during pregnancy, regardless of their general conditions and the fact that one of the previously listed sensitizing conditions have occurred.**

The Emilia Romagna region, in implementing the "National Guidelines for Assistance in Physiological Pregnancies" dated November 2010 with DGR 1704/2012, has established that the ***"anti-Rh(D) immunologic preventive treatment must be offered as a routine treatment to pregnant women who are Rh negative, and not sensitized, at 28 weeks of pregnancy."***

NORMAL PROGRESS OF THE TREATMENT PROPOSED

This preventive treatment has not demonstrated dangerous effects on the fetus, the newborn, or during the progress of the pregnancy.

OBTAINABLE RESULTS FROM THE TREATMENT

At the time of birth, The anti-D preventive treatment reduces by 90% the probability of producing maternal antibodies that attack the red blood cells of the newborn before and after birth.

The immunologic preventive treatment at 28 weeks reduces the percentage of immunizations, during the third trimester of pregnancy, by 1% to 0.2%.

REASONABLY PREDICTABLE RISKS

The preventive treatment does not cause side effects on the newborn, neither before nor after birth.

Anti-D immunoglobulin is a derivative of human blood. The blood donations from which the immunoglobulin derives are controlled according to current provisions of law. Notwithstanding this, it is not possible to entirely exclude risks from transfusions, nor side effects, including the possibility of transmitting infectious diseases, although currently considered extremely low (1 case in every 10 trillion doses injected).

Undesired effects deriving from administering anti-D immunoglobulin to mothers are rare and may include pain, rash, and itching in the injection site, fever, muscle pain, headaches, nausea, vomit, low blood pressure, and allergic reactions.

Other exceptional results or complications reported by international literature cannot be excluded.

Interference on the capacity to drive or use machinery has not been reported.

POSSIBLE ALTERNATIVE TREATMENTS

There are no other treatments reported that replace the anti-D preventive treatment.

CONSEQUENCES ARISING FROM REFUSING THE PREVENTIVE TREATMENT

17% of Rh negative women that do not undergo anti-D immunoglobulin treatment during pregnancy or after birth will develop anti-D antibodies that may, usually in future pregnancies, lead to a certain anemia known as hemolytic disease of the newborn that, in more severe cases, can lead to the intrauterine death of the fetus.

PRELIMINARY INDICATIONS FOR THE PATIENT

Before undergoing the anti-D preventive treatment, an indirect Coombs Test must first be performed, in order to detect the presence of anti-D antibodies in the mother's blood. In the event it is positive, the treatment will not be carried out.

In the event it is negative, the anti-D immunologic preventive treatment is indicated at the 28th week of pregnancy and then must be repeated within 72 hours from the birth of a Rh positive newborn.

The anti-D immunoglobulin is no longer be detect in the mother's blood after 6-8 weeks from when it is administered.

The persistence of a positive indirect Coombs Test after 6-8 weeks demonstrates a maternal immunization that does not depend upon the preventive treatment . This immunization must, therefore, be carefully looked into since it is caused by other antigens or signifies that the immunologic preventive treatment that was carried out has failed.

It must also be specified that, in the event of another pregnancy, the anti-D preventive treatment must be repeated.

It is important that no doubts exist with regards to the treatment proposed, therefore, we invite you to freely ask any questions regarding anything you believe to be necessary or that you did not comprehend.

I declare to have read and fully understood the information received and what was specified in this document.

□ **I agree**

□ **I do not agree**

to undergo the anti-D preventive treatment.

Signature of patient/tutor _____

Signature of interpreter _____

Signature of parent of a minor exercising parental authority _____

Signature of parent of a minor exercising parental authority _____

I, the undersigned, Dr. _____, declares to have furnished thorough explanations regarding the preventive treatment proposed and I, in all consciousness, believe that these were understood by the patient.

Signature of physician _____ date __/__/__

WITHDRAWL OF CONSENT

I, the undersigned, …….. on (date) __/__/__, withdraw my consent to undergo the anti-D preventive treatment;

my reason being ……..

……..

Physician (signature)…….. Date ……

Patient/tutor (signature) …….. Date ……

Witness (signature) …… Date ……