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Phone number: +420 377 241 529, +420 603 174 793

Next Lab Genetika

INFORMED CONSENT WITH INVASIVE PRENATAL EXAMINATION (AMNIOCENTESIS, CHORIONIC VILLUS SAMPLING)

Patient's name and surname:
Insurance No./Date of birth:
Attending physician:

Dear Madam,
Based on clinical examination, pregnancy screening tests, family history, your age, or ultrasound findings, your fetus is at increased risk of a serious congenital disease. Therefore, a prenatal fetus examination (amniocentesis/chorionic villus sampling) is recommended. The aim of this examination is to collect a small amount of amniotic fluid or chorionic villi and to determine the genetic makeup of the fetus (number and structure of chromosomes, detailed chromosome examination or other molecular genetic tests according to the personal or family history).

PROCEDURE DESCRIPTION

The biopsy of chorionic villi is performed between 10 - 13 weeks of gestation, the sampling of amniotic fluid between 15 - 22 weeks of gestation (exceptionally at a later stage of pregnancy). The procedures are performed at our clinic on an outpatient basis, under sterile conditions and in a lying position. Under ultrasound control, a thin needle is inserted into the uterine cavity through a puncture in the lower abdomen, the tip of which is constantly checked by ultrasound. Approximately 20 ml of amniotic fluid is collected, which is a small volume that is quickly replenished. In the case of chorionic villus sampling, the needle is introduced into the placental area. The sampling resembles a blood draw; it is perceived as blunt pressure. When sampling chorionic villi, the injection site may be numbed with a small amount of local anaesthetic on consulting the physician. The whole procedure takes a few minutes. In pregnant women with Rh negative blood group, an injection of anti-D gammaglobulin will be given to prevent immune collision during the next pregnancy.

ALTERNATIVE PROCEDURE

- Not to undergo invasive diagnostics that determines the genetic makeup of the fetus, and accept the health status of the child.
- Undergo cordocentesis - cord blood collection. Blood is drawn through the abdominal wall of the pregnant woman; the risk of complications is approximately twice as high relative to amniocentesis/chorionic villus sampling.
- Ultrasound examination of the fetus aimed at the presence of developmental abnormalities indicating that the fetus might develop a congenital disease. The ultrasound examination does not replace genetic analysis enabled by amniocentesis/chorionic villus sampling.
- NIPT (non-invasive prenatal testing) of the fetus to exclude trisomy(ies) of chromosome(s) 13, 18, 21 and the sex chromosomes (X, Y) from peripheral blood of the pregnant woman. This examination does not completely replace invasive prenatal testing and is inappropriate in some pregnant women; it is even contraindicated in certain cases.

COMPLICATIONS

Based on recent studies, the risk of unintended pregnancy loss linked to amniocentesis is very low, ranging from 0.1 to 0.5%, for physiologically proceeding pregnancies. The risk of miscarriage upon chorionic villus sampling ranges from 0.5 to 1%. Possible complications of the procedure include amniotic fluid leakage, spotting to bleeding, uterine cavity infection, premature onset of uterine activity. Injury to the organs of the small pelvis of the mother, allergic complications, and fetal injury are described as being very rare. Isolated complications include the necessity to perform more than one injection to obtain enough amniotic fluid or the necessity to repeat collection due to failure to culture fetal cells and successfully examine chromosomes. After the procedure, one may experience pain in the lower abdomen, which usually subsides within 2 days. In the event of the potential complications mentioned above, it is necessary to have an examination at a gynaecological outpatient clinic in a hospital or by the attending gynaecologist. In case of any complications, please inform us by phone.

Adresa pracoviště:
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DETAILS OF LIMITATIONS IN THE USUAL WAY OF LIFE

Following the procedure, we recommend 2 - 3 days of proper rest at home. Pregnant women should avoid physically strenuous activity for 2 - 3 weeks. A week's sick leave, issued by your attending gynaecologist, is appropriate.

RESULTS OF AMNIOCENTESIS/CHORIONIC VILLUS SAMPLING

The preliminary result of the analysis (QF PCR to exclude trisomy(ies) of chromosome(s) 13, 18, 21, X, and Y) is obtained by 2 - 3 working days. Complete examination results (karyotype, aCGH, or other molecular genetic tests) are available approximately 3 - 4 weeks later. The results may be consulted with a medical geneticist. Normal results of an invasive prenatal examination do not exclude that your child might suffer from another type of congenital developmental defect or other disease that could not be detected by ultrasound or other examination. We will send the results to your address.

FURTHER PROCEDURE AFTER THE EXAMINATION

After the procedure, the pregnant woman is returned to the care of her attending gynaecologist for further monitoring or, in indicated cases, to our outpatient clinic. A follow-up ultrasound examination of the fetus is carried out based on the recommendation of the gynaecologist performing the sampling.

PATIENT'S STATEMENT

I declare that I have been fully and thoroughly informed about the planned procedure (amniocentesis/ chorionic villus sampling). The objective, expected benefits, and potential complications of the procedure were explained to me. I have been comprehensively informed of possible alternative procedures and the consequences of not undergoing the procedure. All my questions were answered and I have no unclarified issues about the planned procedure. I fully understand the instructions and consent to the invasive prenatal examination, including additional preventive measures following the procedure. This consent is granted of my own free will and without any coercion whatsoever.

PHYSICIAN'S STATEMENT

I declare that I have, in consistence with the current state of knowledge, informed the patient in detail about the planned procedure and its potential complications, and that I have answered any questions.

Physician's signature:.....Date:.....

Signature of the examined woman
(or of her legal representative):.....Date:.....