IMITAS

Rijksinstituut voor Volksgezondheid en Milieu
Ministerie van Volksgezondheid, Welzijn en Sport

Information and informed consent form

IMITAS study – a study of the 13-week scan

Dear madam,

With this letter we ask for your consent to participate in a medical scientific study: the IMITAS study – a study of the 13-week scan. Contained within this letter you will find important information about the study and an informed consent form. By now you will have received the general information brochure "*The 13-week scan and the 20-week scan"* from your obstetric care provider. During an appointment with your obstetric care provider, you will have been told about the 13-week scan and what participating in this study would mean for you. Below, we have provided the most important information about the study for you to read again. If you decide you would like to participate, you can sign and submit the informed consent form at the clinic of your obstetric care provider. The informed consent form can be found in Appendix 1.

General Information about the 13-week scan

- The 13-week scan is an optional medical examination available to all pregnant women aged 16 years or older, performed between week 12 and 3 days and week 14 and 3 days of the pregnancy. You are not required to have a 13-week scan.
- A 13-week scan allows for the early screening for (severe) physical abnormalities of the unborn child. For instance, anencephaly, a condition where most of the brain and spinal cord is missing.
- At 13 weeks gestation the unborn child is smaller and less developed compared to 20 weeks gestation. At 13 weeks, some (severe) abnormalities can be visible. In cases of unborn children with severe abnormalities, the chance of survival through pregnancy, and after birth, are often small.
- Ultrasound examination in general does not provide certainty about the overall health of an unborn child, as there are abnormalities that are impossible to detect by ultrasound. Further, at 13 weeks there are some abnormalities that are not yet present or visible.
- The 13-week scan is an examination to screen for physical abnormalities. For screening for chromosomal abnormalities, you may opt to have a NIPT. However, physical abnormalities may also be visible at the 13-week scan in an unborn child with Down's, Edward's or Patau's syndromes, or any other chromosomal abnormalities. Conversely, in unborn children with chromosomal abnormalities, it is also possible that there are no physical abnormalities visible at the 13-week scan.
- Ultrasound scans are safe for you and your unborn child. The scan doesn't hurt and your unborn child will feel nothing.

General Information about the scientific IMITAS study

- You can only opt to have the 13-week scan if you participate in the national scientific IMITAS study.
- The aim of the scientific study is to examine whether the advantages of the 13-week scan outweigh the disadvantages. On one hand, it seems beneficial for women to be aware of a severe physical abnormality in their unborn child early on in the pregnancy. She will have more time for further examinations, and to decide what she will do considering the results of these examinations. On the other hand, an examination so early in the pregnancy can cause additional anxiety and worries.
- The IMITAS study will examine the results of 13-week scans in the Netherlands and the experiences of both pregnant women and their healthcare professionals. Following the study, it will be decided whether the 13-week scan will be introduced permanently into the prenatal care offer in the Netherlands. Some examples of the questions that will be answered by a team of researchers in this big national study are: How many pregnant women opt to have the 13-week scan? Why do, or don't, pregnant women choose to have this scan? How do pregnant women and their partners experience the 13-week scan? What are the opinions of healthcare professionals?
- By opting to have the 13-week scan, your data and results will be available in your medical file for your obstetric care provider. Your data will also be available in a secured national database (Peridos). Your pregnancy outcome will be registered in the national obstetric registration (Landelijke Verloskundige Registratie) in Perined. Perined is an organization to whom midwifes, general practitioners, gynaecologists and paediatricians register information about all pregnancies and deliveries in the Netherlands (www.perined.nl). The IMITAS researchers can make a request to obtain this information from these data registers. Furthermore, the IMITAS researchers can contact you directly to ask you to participate in the study, for example by completing a survey. If you decide to participate, your information, results and responses will be used and saved.
  For more information about the use of your data: www.13wekenecho.org (IMITAS) or/and www.pns.nl (Peridos).

Appendix 1: Informed Consent Form

By signing this form, you give your consent to the IMITAS researchers to use your data for scientific study.

I have read this information form, the general information brochure "*The 13-week scan and the 20 week scan",* the general information about the 13-week scan on www.pns.nl, and the specific information about the IMITAS study on the website www.13wekenecho.org. I am aware of the mode and purpose of the 13-week scan, how it is carried out and of the possible consequences. All of my questions about the study have been sufficiently answered.

Scientific Study

- I opt to have the 13-week scan. I know that this scan is offered exclusively in the research setting of the IMITAS study. I am aware that the study examines the possible advantages and disadvantages of the 13-week scan. I have been informed adequately about the IMITAS study.
- I know that taking part in the IMITAS study is voluntary. I have had enough time to decide to participate. I know that I can withdraw from, or stop taking part in, the study at any time without explanation.
- I give consent to the IMITAS researchers to contact me directly to ask me to participate in the study. I consent to be asked to give on my opinion on the 13-week scan, or the consequences of the 13-week scan, for me and my pregnancy, by survey or interview.

Privacy

- I give my consent to the IMITAS researchers to obtain information from Peridos, including my personal data, the result of the 13-week scan, results from other screening tests (e.g. 20-week scan and/or NIPT) and other additional examinations (e.g. GUO and genotyping).
- I give my consent to the IMITAS researchers to contact me directly, or via my obstetric care provider, to request additional information about the course of my pregnancy or pregnancy outcome.
- I give my consent to the IMITAS researchers to store my coded research data for 20 years after the end of the study, and I understand that this data will be destroyed after this period.
- I give my consent to the IMITAS researchers to request my medical information from my healthcare professional(s) and that the data about the course and outcome of my pregnancy can be used for the IMITAS study.
- I consent to the use of my data in other potential additional studies concerning prenatal screening, additional diagnostic tests, pregnancy, and pregnancy outcomes, such as research on the consequences and reliability of the 13-week scan, and I give consent that this information can be used.
- I give my consent to the IMITAS researchers to request information about the outcome of my pregnancy from Perined and to link these data to the other research data.

I give consent to participate in the IMITAS study:

Name of participant: _____ Date of birth: [_____] [_____] [_____]

Signature: _____ Date: [_____] [_____] [_____]

Signature obstetric care provider / counsellor

I confirm that I have fully informed the participant about the study. If new information becomes available during the study period that may affect the participants' willingness to consent to participate, I will inform the participant in a timely manner.

Name obstetric care provider / counsellor: _____

Signature: _____ Date: [_____] [_____] [_____]

The participant will receive a copy of this form. A signed form will be kept in the research file of the healthcare provider/counsellor for 20 years.