Patient information Quadruple P SCREENING Study

Measurement of the cervical canal during the 20-week ultrasound scan

Introduction

You have an appointment for the 20-week ultrasound scan: an ultrasound investigation to detect congenital/structural anomalies of the baby. The baby will be displayed on the screen by ultrasound waves through your abdomen. This is a completely safe investigation. During this scan it is also possible to make a vaginal ultrasound to measure the cervical canal. The cervical canal, also called the mouth of the womb or the cervix, is the exit of the uterus. Previous research, in the Netherlands and in other countries, has shown that if the cervical canal is shorter without any symptoms (like abdominal pain or blood loss), there is a greater chance of premature delivery. We call a delivery preterm if the baby is born before 37 weeks of gestation (three weeks before the expected date of delivery).

When a baby is born between 32 and 37 weeks, they usually have to be admitted to the paediatric ward. If the baby is born before 32 weeks, they have to be admitted to the neonatal intensive care unit. Preterm birth is related to severe health problems for the children and usually involves a hospital admission of several weeks. Because of these severe health related problems to preterm birth, a lot of research has been performed to prevent preterm birth. Therefore, it is important to investigate as soon as possible, if a pregnant woman is at risk.

Measurement of the cervical canal

One of those risks is a shorter cervical length during the 20 week ultrasounds can. During this investigation, we propose to measure the length of the cervical canal. In this way, we can make an estimation if you have a higher risk of a premature delivery. If the cervical canal is 35mm or shorter, we speak of a shorter cervical canal.

A shorter cervical canal and then?

Research has shown that some treatments are successful in preventing preterm birth in women with a shorter cervical length. Currently, in The Netherlands treatment is only available in context of the Quadruple P study (https://zorgevaluatienederland.nl/evaluations/quadruple-p). In this research study, two treatments are compared, namely: 1). daily vaginal medication, called progesterone, to help contract the cervix and 2). a mechanically way by using a pessary: a silicon ring that will be placed around the mouth of the womb inside the vagina. If you would like to know more about this treatment study, your ultrasonist, midwife or gynaecologist will refer you to the closest hospital where they perform this study.

Aim of this screening study

By measuring the length of the cervical canal, we examine whether you have a greater risk of giving birth prematurely. In addition, we try to evaluate whether certain risk factors are of influence on the length of the cervical canal and the time of delivery, by collecting your personal details and information about the delivery. For that reason, we specifically ask your permission to collect and use the cervical length measurement, the information of questionnaire and the details of your delivery.

Study design and load

The cervical length measurement has to be performed by a vaginal ultrasound. To that end, the ultrasonist will bring in a thin probe inside the vagina. In most cases, this does not hurt. During this procedure, it is better to have an empty bladder. The measurement only takes a few minutes.

Possible benefits of this screening study

It is not sure that you will have personal benefit by participating in this screening study. In the future, the outcomes of this screening study can be of use and benefit for other pregnant women.

Eventual risks of this screening study

So far, no risks are known for measuring the length of the cervical canal by a vaginal ultrasound. This screening study is exempt of a mandatory study subject insurance by the Medical Ethical Commission of the Amsterdam UMC, because you are not at risk when participating in this study.

Participation is voluntary

This is completely voluntary measurement. If you do not wish to participate, you can tell this to the ultrasonist during the 20-week anomaly scan.

Data confidentiality

You can be assured that all your personal data and that of your child will be treated confidentially. Besides the information of the questionnaire, we will also collect your address and postal code, so we will be able to request the details of the delivery from the Stichting Perinatale Registratie Nederland (www.perined.nl). Your personal details will be sent to the research team in het AMC and then encrypted. Thereafter, data can only be traced back to you with the use of a key code. Only the research team will have access to this key code. If it is necessary to verify if the research has been conducted well and reliably, monitors hired by the research group or national supervisory authorities, like the Health Care and Youth Inspectorate (IGJ), might get access to all of your personal data and that of your child, including the unencrypted data. The will keep the information and your data secret. In the reports and publications of this research, the used data cannot be traced back to you. The data will be stored for 15 years at the research location and destroyed afterwards.

Finally

If you have any questions of if you would like some advice about participating in this screening study, you can approach an independent physician who is not involved in this study: Dr. A. Timmermans, gynaecologist (tel: 020-5663654). For any remaining questions, please contact the project leader of this study, prof. dr. E.va Pajkrt or your ultrasonist, midwife or gynaecologist.

Should you decide to participate in this screening study, please sign the informed consent and fill in the questionnaire. Thanking you in advance!

Prof. dr. E. Pajkrt, gynaecologist – perinatologist Amsterdam UMC (tel:020-5661297).
Lotte van Dijk, researcher Quadruple P SCREENING study (quadruplep@amsterdamumc.nl)

Informed Consent form for participation in the scientific research:
Quadruple P SCREENING study
Measurement of the cervical canal during the 20-week ultrasound scan

- I was informed about the study sufficiently. I have studied the written information thoroughly. I was given opportunity to ask questions about the research. I was able to think the research through thoroughly.
- I give my consent to the sending of the questionnaire with my personal data (including address and postal code) to the research team and my consent to encryption of my personal data at the research location afterwards. In this way, the details of the delivery can be obtained at the Stichting Perinatale Registratie Nederland.
- I give my consent to the storage of my data and of my child for a period of 15 years, after the research has been finished.
- I know that some people can access my personal data and that of my child. These people are mentioned in this information letter. I give my consent for this access by the persons.
- I have the right to withdraw my consent at any time, without providing a reason.
- I agree to participate in the study.
- I **DO / DO NOT** give my consent to contact me by telephone or in writing for a follow-up research after this research. *(circle as appropriate)*

Name: Date of birth:

Signature: Date:

The undersigned declares that the above named person was informed about the above-mentioned study both in written form and orally and the later-described questionnaire and measurement in filled in correctly.

Name: Signature:

Date: Practice/Hospital:

First and last name patient:

Date of birth:

Address (street, number, postal code):

QUADRUPLE P SCREENING STUDY

To be completed by expectant mother

I. Current pregnancy:

1. Due date based on first trimester ultrasound: ____ - ____ - 20_____ *(dd-mm-yyyy)*
2. Singleton/Multiple *(circle as appropriate)*
   When multiple: ○ Twin: dizygotic twins *(fraternal)*
   ○ Twin: monozygotic, both own amniotic sac *(identical)*
   ○ Twin: monozygotic, shared amniotic sac *(identical)*
   ○ Triplet: _____

II. Obstetrical history

1. I've been pregnant _____ times *(total number)*
2. Number of deliveries after 16 weeks gestation: _____ *(total number)*
3. Caesarean section: ○ No ○ Yes: _____ *(total number)*
4. Miscarriage: ○ No ○ Yes: _____ *(total number)* of which curettage:___ *(total number)*
5. Abortion: ○ No ○ Yes: _____ *(total number)* of which curettage:___ *(total number)*
6. Last pregnancy: normal delivery/ caesarean section/ miscarriage (with/ without curettage)/ abortion (with/ without curettage) *(circle as appropriate)*
7. Date termination of last pregnancy: ____ - ____ - 20____ *(dd-mm-yyyy)*
8. Gestation of last pregnancy: _____ weeks and _____ days

III. Family history

1. Expectant mother born *before/ after* 37 weeks *(circle as appropriate).*
   namely at ____ weeks and ____ days.
2. Brother(s) and/or sister(s) of expectant mother born before 37 weeks?
   ○ N.A. ○ No ○ Yes:___*(total number)*
3. Sister(s) of expectant mother delivered before 37 weeks?
   ○ N.A. ○ No ○ Yes:___ *(total number)*

IV. General health information

1. Length: _____ cm Weight before pregnancy: _____ kg
2. Smoking: ○ No ○ Yes: ____ *(cigarettes per day)*
3. Diabetes: ○ No
   ○ Yes: Type 1 / Type 2 / pregnancy diabetes *(circle as appropriate)*
   Treatment: None / Diet / Insulin / other: _____ *(circle as appropriate)*
4. Repeated cystitis in the last 12 months (needed treatment): ○ No ○ Yes: _____ *(total number)*
5. History of surgery of the cervical canal/cervix: ○ No
   ○ Yes: Lis excision/conisation*(circle as appropriate)*

To be completed by the ultrasonist

1. Cervical length: _____ mm measured at ____ - ____ - 20 ____ *(dd-mm-yyyy)*
2. Gestational age at day measurement: _____ weeks ____ days