An observational study to investigate the puborectalis muscle by ultrasound in pregnancy and after delivery

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1. Our finding that measuring MEP at 12 weeks gestation could be an important marker for normal or abnormal delivery which needs to be confirmed in a separate study. 2. To measure the echogenicity of the uterus (myometrium), cervix and vastus...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Observational non invasive

Summary

ID

NL-OMON50211

Source
ToetsingOnline

Brief title
PURE - PUboRectalis Echogenicity during pregnancy and after delivery

Condition

- Muscle disorders
- Pregnancy, labour, delivery and postpartum conditions

Synonym
Difference in muscle composition, impossibility for vaginal delivery

Research involving
Human

Sponsors and support

Primary sponsor: Gynaecologie
Source(s) of monetary or material Support: Overgebleven studiegeld.

Intervention

Keyword: Echogenicity, Puborectalis muscle, Regeneration, Ultrasound

Outcome measures

Primary outcome

MEP at 12 weeks gestation in the different groups (vaginal delivery versus secondary Caesarean section due to failure of progress).

Secondary outcome

Mean echogenicity of the cervix, myometrium and vastus lateralis muscle at 12 weeks gestation. Mean echogenicity and distribution of different echogenicity of the puborectalis muscle and the change in echogenicity during recovery/regeneration after vaginal delivery.

Study description

Background summary

The pelvic floor plays an important role in supporting pelvic organs in women thereby preventing symptoms like urinary or fecal incontinence and pelvic organ prolapse. This association is well-known. Less attention has been paid to the role of the pelvic floor in pregnancy, during childbirth and after delivery. During pregnancy the pelvic floor will have to resist progressive forces on one hand, but on the other hand has to adapt to allow maximum dilatation during delivery. How this adaptation process works over time has hardly been studied. During engagement and passage of the fetal head at the time of delivery the pelvic floor muscles are stretched and compressed against the pelvic sidewall. This will induce injuries. Only one recent study (van Delft) looked at the ultrasound image of the puborectal muscle 3 days after delivery and noticed the occurrence of hematomas and abruptions of the muscle from its attachment at the pubic bone. After vaginal delivery recovery of the pelvic floor muscles starts, but this process has not been studied in itself or compared to recovery after caesarean section.
The pelvic floor consists of striated muscles and connective tissue (part loose and part condensed into ligaments). Not only the pelvic floor undergoes changes, but also the uterus, cervix and other pelvic structures must

adapt to facilitate delivery. With three-dimensional (3D) ultrasound scans, it is possible to visualize the pelvic floor muscles, particularly the puborectal part of the levator ani. A new ultrasound parameter to assess muscle integrity and composition is echogenicity. In a cohort study of primigravid women at the UMCU a technique to study the mean echogenicity of the puborectalis muscle (MEP) was developed in collaboration with the Technical Medicine Department of the University of Twente. This mean echogenicity of the puborectalis muscle was studied, amongst others, in relationship to pregnancy outcome. Our initial results strongly suggest that there is an association between echogenicity of the puborectalis muscle at 12 weeks gestation and mode of delivery. In other words, the MEP at 12 weeks gestation could serve as an important predictor for a Caesarean section due to failure to progress. It is unclear if this difference in echogenicity is locally confined to the puborectal muscle or constitutional.

Study objective

1. Our finding that measuring MEP at 12 weeks gestation could be an important marker for normal or abnormal delivery which needs to be confirmed in a separate study.
2. To measure the echogenicity of the uterus (myometrium), cervix and vastus lateralis muscle at 12 weeks gestation in association with mode of delivery
3. The process of normal regeneration after vaginal delivery needs to be studied. Ultrasound is easy to use, cheap and repeatable. This information on normal recovery is crucial for our regenerative medicine program. In the latter we focus on techniques to enhance regeneration after delivery in order to minimize permanent damage. Using echogenicity as a marker is promising, but needs to be studied.

Study design

Prospective cohort study.

Study burden and risks

All women participating will receive their regular prenatal and postnatal care. The burden associated with participation is an extra ultrasound of the pelvic floor which will be scheduled during a routine visit if possible (range 8-14 weeks). The pre-selected group will have 8 extra ultrasounds. 20 patients getting a primary caesarean section, will undergo 3 ultrasound examinations (1 before and 2 after delivery). Accidental findings will be reported.

Contacts

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Selecteer

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Nulliparous women
Singleton pregnancy
Good knowledge of Dutch language
Signed informed consent

Exclusion criteria

Age < 18 years
History of pelvic organ prolapse or incontinence surgery
History of surgery in the uterus implying indication for Caesarean section
(Except for the group of 20 patients undergoing a primary caesarean section)

Connective tissue disease
Not allowed to do a maximum Valsalva maneuver because of cardiac or pulmonary disease

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-03-2015
Enrollment:	326
Type:	Actual

Ethics review

Approved WMO Date:	08-12-2014
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	21-01-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	24-08-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	

Date:	26-01-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-07-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-03-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-11-2020
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25598
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL49202.041.14
OMON	NL-OMON25598

Study results

Date completed:	23-08-2017
Actual enrolment:	306