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

Published: 08-12-2014 Last updated: 15-05-2024

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.

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## 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.

To measure the echogenicity of the uterus (myometrium), cervix and vastus lateralis muscle at 12 weeks gestation in association with mode of delivery
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

**Public** Selecteer

Heidelberglaan 100 Utrecht 3584 CX NL **Scientific** Selecteer

Heidelberglaan 100 Utrecht 3584 CX NL

# **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)

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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
Туре:	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	24.00.2015
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: Nationaal Trial Register Title:

## In other registers

Register	ID
ССМО	NL49202.041.14
OMON	NL-OMON25598

# **Study results**

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