De musculus puborectalis tijdens de zwangerschap en na de bevalling.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25598

Source
NTR

Brief title
PURE PUboRectalis Echogenicity

Health condition

Zwangerschap / Pregnancy
Bevalling / Delivery
Niet vorderende uitdrijving / Failure to progress
Spierherstel / Muscle regeneration

Sponsors and support

Primary sponsor: Prof. Dr. C.H. van der Vaart, gynaecologist
University Medical Centre Utrecht
Source(s) of monetary or material Support: Prof. Dr. C.H. van der Vaart, gynaecologist
University Medical Centre Utrecht

Intervention

Outcome measures

Primary outcome

Mean echogenicity of the puborectalis muscle (MEP) at 12 weeks gestation in the different delivery 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 in the two groups. Mean echogenicity and distribution of different echogenicity of the puborectalis muscle and the change in echogenicity during recovery/regeneration after vaginal delivery.

Study description

Study objective

The mean echogenicity of the puborectalis muscle in nulliparous women at 12 weeks gestation is lower in women delivering by Caesarean section due to failure to progress compared to women delivering vaginally.

Study design

Ultrasound assessment at 12 weeks pregnancy.
Twenty patients will undergo intensive postpartum follow-up 1 day, 1 week, 2 weeks, 3 weeks, 4 weeks, 6 weeks, 12 weeks, (16 weeks), 18 weeks and 24 weeks after delivery.

Intervention

Performing ultrasound assessment of the pelvic floor, cervix, myometrium and vastus lateralis muscle at 12 weeks gestation. Twenty patients of the UMCU (UVC/WKZ) will have intensive follow-up after vaginal delivery to assess regeneration after delivery trauma.

Contacts

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Eligibility criteria

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 (indication for 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
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	06-03-2015
Enrollment:	306
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-11-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50211
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4754
NTR-old	NTR4882
CCMO	NL49202.041.14
OMON	NL-OMON50211

Study results