3D Transperineal Ultrasound Imaging of the changes of the pelvic floor muscles during labour

Published: 04-02-2009
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Primary Objective: 3D ultrasound imaging of the morphological changes of the pelvic floor and the arising of possible defects during labour.

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

Summary

ID

NL-OMON32870

Source
ToetsingOnline

Brief title
3D Ultrasound Imaging of the pelvic floor during labour

Condition

- Other condition
- Maternal complications of labour and delivery

Synonym
levator ani, pelvic floor, sphincter ani

Health condition

urine/faecale incontinentie en prolaps (bekkenbodem)

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 3D ultrasound, labour, m levator ani, pelvic floor

Outcome measures

Primary outcome

Not applicable (observational study)

Secondary outcome

Not applicable (observational study)

Study description

Background summary

Vaginal delivery may cause denervation of the pelvic floor as well as direct injury to muscles and connective tissue. These injuries may lead to the development of stress urinary incontinence, faecal incontinence, voiding difficulties, chronic obstipation and/or urogenital prolapse. Until now most studies focused on anal sphincter rupture. Recently researchers have shown more interest into injuries of the levator ani. Most authors assume that such defects arise at the time of crowning of the fetal head1. However, proof for this hypothesis has been lacking due to the inherent limitations of magnetic resonance imaging and the logistic problems of performing MRI in young asymptomatic nulliparous pregnant women in late gestation. Nowadays 3-dimensional and 4-dimensional pelvic floor ultrasound is capable of demonstrating the pubovisceral muscle complex at little cost and with minimal inconvenience to the patient.
The 3D ultrasound will enable us to examine what happens at which moment to the pelvic floor during labour.

Study objective

Primary Objective: 3D ultrasound imaging of the morphological changes of the pelvic floor and the arising of possible defects during labour.

Study design

This study is designed as a pilot observational study and will be conducted in the Erasmus Medical Centre. We will include ten healthy primimara women and perform a 3-dimensional transperineal pelvic floor ultrasound once before labour, two times during labour (3-5 cm dilation and 5-9 cm dilation), and three times after labour (2-24 hours after delivery, 6 weeks after delivery, 3 months after delivery). By this means we will hopefully learn more about the pelvic floor dynamics during labour, our special interest concerns the levator ani.

Study burden and risks

We will perform six transperineal 3D ultrasound examinations in all subjects. The first examinations will be performed before labour, the second and third during labour. They will have no influence on the progress or timepath of labour. There are no further risks for mother or child.
The first examination after labour will still take part in the delivery room (2-24 hours after delivery). The ultrasound six weeks after delivery will be combined with the general follow-up. There will be one extra appointment for the examination three months after the delivery.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

primiparous women
>37weeks PMA
induction of labour

Exclusion criteria

Multiparous women
<37 weeks PMA
malpresentation (non cephalic presentation)
previous pelvic floor trauma

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):	01-11-2009
Enrollment:	10

Type:	Actual

Ethics review

Approved WMO Date:	04-02-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-12-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL24205.078.08