An observational study to determine the association between stress urinary incontinence and levator avulsions

Published: 21-10-2008
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To investigate the association of anatomical defects with the occurrence of stress urinary incontinence.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational invasive

Summary

ID

NL-OMON32163

Source
ToetsingOnline

Brief title
association between SUI and levator avulsions

Condition

- Tendon, ligament and cartilage disorders
- Pregnancy, labour, delivery and postpartum conditions

Synonym
pelvic floor defects, stress urinary incontinence

Research involving
Human

Sponsors and support

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

Intervention

Keyword: levator avulsions, pelvic floor, pregnancy, stress urinary incontinence

Outcome measures

Primary outcome

Stress urinary incontinence at 12 and 36 weeks of gestation and 6 months

postpartum.

Secondary outcome

Association between anatomical and mobility disorders of the levator ani

complex and other urogenital symptoms.

Association between pregnancy and childbirth related factors and the presence

of levator injuries

Study description

Background summary

Urinary incontinence (UI) is a common problem in adult women, with an estimated prevalence that ranges between 25 and 60%. Childbirth has been shown to be one of the major risk factors for developing urinary incontinence. Almost half of incontinent women suffer from urine loss during physical exercise, the so-called Stress Urinary Incontinence (SUI). This SUI is caused by the occurrence of insufficient support of the urethra, but its pathophysiology has not been fully elucidated. There is little information on the association between the occurrence of SUI and anatomical injuries caused by pregnancy and/or delivery.

Study objective

To investigate the association of anatomical defects with the occurrence of stress urinary incontinence.

Study design

prospective observational study

Study burden and risks

The extent of burden for participating women will be minimal. During the routine prenatal care and the visit at 6 months postpartum, an additional ultrasound will be performed. Ultrasound examination will take 10-15 minutes. Adverse effects of ultrasound during pregnancy are not described.

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

nulliparous women
singleton pregnancy

good knowledge of Dutch language

Exclusion criteria

History of urinary and or faecal incontinence
Previous prolapse or anti-incontinence surgery
Connective tissue disease
Neurological disorders
Not allowed to do a maximum valsalva manoeuvre

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-04-2009
Enrollment:	270
Type:	Actual

Ethics review

Approved WMO

Date:	21-10-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL22685.041.08