Learning curve and applicability of 3D/4D translabial ultrasound for diagnosing levator ani defects

Published: 12-01-2011 Last updated: 04-05-2024

The first aim is to study the learning curve of a student and a gynecologist for performing a translabial 3D ultrasound scan and of the capacity to read a scan and judge the integrity of the levator ani. Furthermore a comparison will be made between...

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

Summary

ID

NL-OMON36639

Source ToetsingOnline

Brief title LCA study

Condition

• Other condition

Synonym pelvic organ prolapse

Health condition

prolaps en incontinentie

Research involving

Human

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Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht **Source(s) of monetary or material Support:** Ministerie van OC&W

Intervention

Keyword: learning curve, levator defects, translabial 3D-ultrasonography

Outcome measures

Primary outcome

 How many 3D ultrasoundscans of the pelvic floor does a gynecologist with experience in gynecological ultrasound need to perform to visualise all essential referencepoints to reach an inter observer agreement with a weighted kappa of 0.8 compared to an expert.
How many 3D ultrasoundscans of the pelvic floor does a student with no

2. How many 3D ultrasoundscans of the pelvic floor does a student with no

ultrasound experience need to perform to visualise all essential

referencepoints to reach an inter observer agreement with a weighted kappa0.8.

compared to an expert.

3. How many recorded ultrasoundscans does a gynecologist with experience in gynecological ultrasound need to read to learn to judge the integrity of the levator ani to reach an inter observer agreement with an ICC of 0.6. compared to an expert.

4. How many recorded ultrasoundscans does a student with ultrasound experience need to read to learn to judge the integrity of the levator ani to reach an inter observer agreement with an ICC of 0.6. compared to an expert.

Secondary outcome

5. What is the inter test agreement (weighted kappa) between a Voluson GE Kretz

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and Toshiba ultrasoundmachine in visualising the reference points essential in

3D ultrasound of the pelvic floor.

6. What is the inter test agreement (ICC) between a Voluson GE Kretz and

Toshiba ultrasoundmachine in the judgement of the integrity of the levator

ani.

Study description

Background summary

Levatordefects occur in approximately 20-30% of deliveries. Levatordefects are a risk factor for developing pelvic floor dysfunction and prolapse. Levatordefects are associated with an increased risk for recurrence after surgery. Levatordefects can be diagnosed by 3D/4D translabial ultrasound and by MR imaging. The role of ultrasound in daily care for diagnosing levatordefects in relation to the reference standard MRI has to be assessed. For this assessment and for clinical practice we have to know whether it is necessary that the gynecologists performs and reads the ultrasound scans or someone else can learn to make thes scans and judge them. This study focuses on the learning curve of 3D translabial 3D ultrasound of the pelvic floor to prepare the implementation of pelvic floor ultrasound. All studies described in literature are performed on the Voluson GE Kretz . We need to know whether the knowledge of the software applications for optimizing the images on the Voluson ultrasound machine can be extrapolated to other machines.

Study objective

The first aim is to study the learning curve of a student and a gynecologist for performing a translabial 3D ultrasound scan and of the capacity to read a scan and judge the integrity of the levator ani. Furthermore a comparison will be made between two ultrasound machines to find out whether the knowledge of the Voluson GE Kretz on translabial ultrasound of the pelvic floor can be extrapolated to other machines.

Study design

multicentre prospective observational cohort study

Study burden and risks

Patients that join the study have to visit the hospital one time extra. Ultrasonography of the levator ani has no risk for general health and no radiation is used. The ultrasound exam will be performed by three different docters. No questionnaires and no follow-up appointment are needed. There is no benefit for the patient by joining the study. The costs for travelling and parking will be compensated.

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

women with symptoms of pelvic organ prolapse or incontinence.

Exclusion criteria

younger than 18 people who are not able to understand the information

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2011
Enrollment:	106
Туре:	Actual

Ethics review

Approved WMO	
Date:	12-01-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-06-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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 CCMO **ID** NL33468.068.10