Obstetric anal sphincter injury, a follow-up study on the long term outcome.

Published: 06-06-2014
Last updated: 24-04-2024

Aim of the study is to get informed on the outcome of women treated in the MUMC for obstetric anal sphincter injury between 2005 and 2012. The controlgroup is matched for maternal age at delivery, parity, mode of delivery and child weigth.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anal and rectal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON40501

Source
ToetsingOnline

Brief title
OASIF-MUMC

Condition

- Anal and rectal conditions NEC
- Maternal complications of labour and delivery
- Obstetric and gynaecological therapeutic procedures

Synonym
anal incontinence after obstetric anal sphincter injury

Research involving
Human

Sponsors and support

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

Intervention

Keyword: endoanal ultrasound, manometry, obstetric anal sphincter injury, outcome

Outcome measures

Primary outcome

anal incontinence

Secondary outcome

abnormalities in the sphincter on endoanal ultrasound (persistent defects)

abnormalities in sphincter function om endoanal manometry

risc factors for developing anal incontinence after obstyetric anal sphincter

injury

risk of recurrent obstetric anal sphincter defect in a subsequent vaginal

delivery

incidence of urine incontinence

Study description

Background summary

The last Dutch study on outcome after obstetric anal sphincter injury is published in 2001 and described a prevalence of fecal incontinence after obstetric anal injury of 31%(de Leeuw et al). As a result of publications on the bad outcome of women after obstetric anal sphincter injury there has been a growing attention for this subject the last 20 years. The recognition of sphincter injuries, the importance of both the internal and external sphincter and the pros and cons of different suture techniques have been under the attention. It is possible that the incidence of anal incontinence after obstetric anal sphincter injury has changed and perhaps has improved. Since there is no structural follow-up of these women, the outcome for women in the current time in the netherlands is unknown.

Study objective

Aim of the study is to get informed on the outcome of women treated in the MUMC for obstetric anal sphincter injury between 2005 and 2012. The controlgroup is matched for maternal age at delivery, parity, mode of delivery and child weigth.

Study design

An observational retrospective cohort study and case control study, with prospective follow-up.

Study burden and risks

The endoanal ultrasonography and anorectal manometry are both invasive diagnostic tools, which are painless and without any risk, but can be a burden for a patient undergoing the exams. Filling in the questionnaires is time consuming and can be a burden because personal questions are asked on continence status. The risk for any adverse event in the study is very low. There is no benefit for the subjects in joining the study.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

Debyelaan 25
Maastricht 6202 AZ
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

Debyelaan 25
Maastricht 6202 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- All women with a history of a first-ever obstetric anal sphincter injury in the period 2005-2012.
- Diagnosis and treatment of an obstetric anal sphincter injury in the MUMC
- Willing to give informed consent
- Capable of understanding the Dutch language and the given information
- Minimum age of 18 years ;Control group:
- All women with a delivery in the period 2005-2012 in the MUMC
- No diagnosis and treatment of an obstetric anal sphincter injury.
- Permission to informed consent
- Capable of understanding the Dutch language and the given information
- Minimum age of 18 years

Exclusion criteria

- no Permission to informed consent
- not Capable of understanding the Dutch language and the given information
- age < 18 years

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-06-2014
Enrollment:	665
Type:	Actual

Ethics review

Approved WMO

Date:	06-06-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	23-10-2014
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	ID
CCMO	NL47537.068.13