

are anterior perineum length and partial anal dilatation riskfactors which lead to symptomatic and a- symptomatic sphincter injury?

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Find en give answers on the following questions: If ASR does occur can this be correlated to the seriousness of the maximum partial sphincter dilatation and /or the congenital perineum length?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Observational invasive

Summary

ID

NL-OMON37235

Source

ToetsingOnline

Brief title

outcome of anal sphincter injury due to vaginal delivery

Condition

- Muscle disorders
- Pregnancy, labour, delivery and postpartum conditions

Synonym

anal sphincter rupture; faecal incontinence

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: Erasmus MC opleiding professional master specialised pelvic physiotherapist

Intervention

Keyword: anal dilatation, anal sphincters, delivery, perineumlength

Outcome measures

Primary outcome

symptomatic and asymptomatic sphincter injury

Secondary outcome

perineum anterior length

* at the beginning of the second stage: extension beginning

* during transection of the head(crowning)

- diameter anal gap

* at the beginning of the second stage: extension beginning

* during transection of the head(crowning)

- function external anal sphincter

* 6 weeks postpartum

* 3 months postpartum

- anatomy of the IAS and EAS diagnosed by ultrasound examination

- * 3 months postpartum

- race

- * white

- * black

- * Asian

- * Indian

- age of patient

- BMI

- Medication in pregnancy

- Time of amenorrhoe at confinement

- Onset of labor:

- * spontaneous

- * induced

- duration of cervical effacement and dilatation

- duration of second stage of labor(extension)

- anal diameter

- . end of dilatation

- * duration second stage of labor at transection of the head

- episiotomy

- * length

- rupture (classification according to RCOG, also vaginal)

- presentation
- * head
- * breech presentation (spontaneous/ partial extraction)
- headposition:
 - * occiput anterior
 - * left occiput transverse
 - * occiput posterior
- extraction
 - * vacuum
 - * forceps
- childweight
- circumference head
- way of pushing
 - * effective
 - * paradoxal
- shoulderdystocia
- anaesthesia
 - * none
 - * pethidene (intramuscular)
 - * marcaine (epidural)
 - * other**.
- childbed details
- wound healing
 - * complicated

* uncomplicated

- duration of breastfeeding

- recovery of cycle after*..weeks

Study description

Background summary

outcome of vaginal delivery on the anatomy and function of the anal sphincters

Study objective

Find en give answers on the following questions:

If ASR does occur can this be correlated to the seriousness of the maximum partial sphincter dilatation and /or the congenital perineum length?

Study design

prospective cohort

Study burden and risks

The risks associated with participation are minimal.

The burden is minimal too: we try to combine our evaluations and the interventions pelvic physical therapy with the regular visits to the gynaecologists

Contacts

Public

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NL

Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

primigravida, >18 years, speaking dutch, clinical delivery

Exclusion criteria

sexual abuse, vaginal bleeding in the third trimester, peri anal fistula, intrauterine growth retardation, premature delivery

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):	14-03-2008
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	NL17327.044.07