

# 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?

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Muscle disorders
<b>Study type</b>	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

Medisch Spectrum Twente

postbus 50.000  
7500 KA Enschede  
NL

### Scientific

Medisch Spectrum Twente

postbus 50.000

7500 KA Enschede  
NL

## 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