Anorectal function and the effect of childbirth in patients with M Crohn

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Disease activity, perianal involvement and lesion localisation are important influential parameters making sure no pregnancy is exactly alike and mode of delivery needs to be considered on an individual patient level.A complete anorectal function...

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

Summary

ID

NL-OMON39857

Source
ToetsingOnline

Brief title
Anorectal function, childbirth and M Crohn

Condition

- Anal and rectal conditions NEC
- Pregnancy, labour, delivery and postpartum conditions

Synonym
Feacal incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Anorectaal functie onderzoek voor de bevalling wordt als deel van de academische zorg door de verzekering betaald. Het anorectaal functieonderzoek na de bevalling wordt bij het ontbreken van

klachten door onderzoeker zelf verricht.

Intervention

Keyword: Anorectal function, Childbirth, Colitis Ulcerosa/M Crohn, Feacal incontinence

Outcome measures

Primary outcome

Anorectal function evaluation (questionaires, anal manometry, rectal compliance

and anal endosonography) before and six months after delivery.

Secondary outcome

The effect of child birth on anorectal function regarding

* Perianal involvement

* Complaints

* Disease activity

* Pregnancy outcome

Study description

Background summary

The European Crohn and Colitis organisation (ECCO) guidelines advise that elective caesarean section is indicated for all woman with perianal involvement even though the evidence suggesting harm from vaginal delivery in woman with inactive disease is scarce.

Disease activity, perianal involvement and lesion localisation are important influential parameters making sure no pregnancy is exactly alike and mode of delivery needs to be considered on an individual patient level.

A complete anorectal function evaluation (AFE) in relation to degree of (perianal) involvement prior to delivery could be a tool in predicting functional sphincter outcome and incontinence after vaginal delivery in patients with Crohn*s disease and Colitis Ulcerosa. Thereby contributing to the decision making process surrounding what mode of delivery is the most

appropriate for each patient.

Study objective

Disease activity, perianal involvement and lesion localisation are important influential parameters making sure no pregnancy is exactly alike and mode of delivery needs to be considered on an individual patient level.

A complete anorectal function evaluation (AFE) in relation to degree of (perianal) involvement prior to delivery could be a tool in predicting functional sphincter outcome and incontinence after vaginal delivery in patients with Crohn*s disease or Colitis Ulcerosa. Thereby contributing to the decision making process surrounding what mode of delivery is the most appropriate for each patient.

Study design

Descriptive prospective study.

Study burden and risks

No additional risks are associated with participation for the healthy controls, patients with M Crohn or for patients with Colitis Ulcerosa.

In providing the best possible care it is of the utmost importance to know what mode of delivery is best suited for each individual patient.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1118
Amsterdam 1081 HZ
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1118
Amsterdam 1081 HZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Age 18 years and older
* Informed Consent (IC)
* Pregnancy
* Healthy controls, patients with Colitus Ulcerosa, patients with M Crohn

Exclusion criteria

* Refusal of participation

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-04-2013
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	26-04-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL42002.029.12

Study results

Date completed:	20-08-2015
Actual enrolment:	12

Summary results
Trial ended prematurely