Genetics of pelvic organ prolapse; identification of specific gene defects in patients and their family members.

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21396

Source
NTR

Brief title
Genetics of pelvic organ prolapse

Health condition

Pelvic floor,
pelvic organ prolapse,
genetic polymorphism,
collagen

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The presence of the COL3A1 polymorphism in first and second degree family members of the index patients with the homozygous COL3A1 polymorphism.

Secondary outcome

The presence of pelvic organ prolapse and related conditions (such as inguinal hernia) in first and second degree family members of the index patients with the homozygous COL3A1 polymorphism.

Study description

Background summary

Type III collagen is of special importance in tissue repair following mechanical stretch such as in delivery or pelvic organ prolapse (POP). Type III collagen polymorphisms may therefore result in a decrease in tissue repair and may lead to impaired tensile strength of ligaments and supportive tissues. Chen and co-workers have suggested that a COL3A1 polymorphism in exon 30 was related to POP in Taiwanese women. Our research group recently confirmed this finding in a larger population of 202 Dutch POP patients and 102 parous controls. The odds ratio for the presence of POP in a woman with this homozygous COL3A1 polymorphism is 5.0 (95% confidence interval 1.4; 17.1).

Our hypothesis is that the COL3A1 polymorphism is a inheritable genetic defect, responsible for increased familial susceptibility to pelvic organ prolapse and other collagen-mediated diseases.

Study objective

The COL3A1 polymorphism is a inheritable genetic defect, responsible for the increased susceptibility to pelvic organ prolapse in women.

Study design

1. A blood sample of all subjects will be used for the detection of the COL3A1 polymorphism by means of PCR followed by RFLP analysis;

2. Prolapse will be assessed by gynaecological investigation of female subjects to complete the POP-Q;

3. Other related conditions will be evaluated by means of a qestionnaire.

Intervention

None.

Contacts

Public
Universitair Medisch Centrum St. Radboud, Afdeling Verloskunde en Gynaecologie. Huispost 791. Postbus 9101
S.L. Lince
Universitair Medisch Centrum St. Radboud, Afdeling Verloskunde en Gynaecologie. Huispost 791. Postbus 9101
Nijmegen 3500 HB
The Netherlands
+31 (0)24-3614726
Scientific
Universitair Medisch Centrum St. Radboud, Afdeling Verloskunde en Gynaecologie. Huispost 791. Postbus 9101
S.L. Lince
Universitair Medisch Centrum St. Radboud, Afdeling Verloskunde en Gynaecologie. Huispost 791. Postbus 9101
Nijmegen 3500 HB
The Netherlands
+31 (0)24-3614726

Eligibility criteria

Inclusion criteria

First and second degree relatives of patients with COL3A1 polymorphism.

Exclusion criteria

1. Genetic diseases with a known increased risk of POP (such as Ehlers Danlos, Marfan and Steinert’s disease);

2. Problems with regards to the patient’s understanding of the study;

3. Age < 18 years.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	22-06-2009
Enrollment:	50
Type:	Unknown

Ethics review

Positive opinion

Date:	05-08-2009
Application type:	First submission

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
NTR-new	NL1825
NTR-old	NTR1935
Other	CMO Regio Arnhem-Nijmegen : 2009/067
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A