COLPOP
'"Collagen metabolism in patients with and without Pelvic Organ Prolapse; a pilot study*

Published: 13-11-2007
Last updated: 08-05-2024

To investigate the collagen metabolism in pelvic floor tissue, pelvic floor-derived fibroblasts, and adipose tissue stem cells in patients with and without pelvic organ prolapse (POP)

Ethical review	Approved WMO
Status	Pending
Health condition type	Connective tissue disorders (excl congenital)
Study type	Observational invasive

Summary

ID

NL-OMON30888

Source
ToetsingOnline

Brief title
COLPOP
Collagen metabolism and pelvic organ prolapse; a pilot study

Condition

- Connective tissue disorders (excl congenital)

Synonym
cystocele, pelvic organ prolaps, rectocele; prolaps

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Adipose tissue stemcells, Collagen metabolism, Fibroblasts, Pelvic organ prolapse

Outcome measures

Primary outcome

Main study parameter/endpoint

·Determination of the production, crosslinking status and degradation profiles

of the different collagen types in patients with and without POP in relation to

age, parity, BMI, and POP status

· Comparison of the collagen metabolism of differentiated stem cells and

vaginal fibroblasts, of patients with and without POP.

Secondary outcome

Secundary study parameters

Not applicable

Study description

Background summary

Genital Prolaps (=POP) is an increasing problem. Treatment modalities are pessary therapy or surgery. In thirty percent of the cases recurrence of the prolapse occurs after surgery. To improve the results of prolapse surgery the use of meshes is introduced, for example synthetic polypropyleen. Meshes maintain their tensile strenght, but have a substantial risk of rejection because they do not dissolve.
Other organic meshes dissolve gradually and do not provoke an immune reaction, i.e. rejection of the mesh. However they loose their tensile strenght and are not effective.
Ideally, treatment of POP should be regenerating the vaginal prolapsed tissue instead of replacing the tissue by a mesh. We have to obtain more knowledge, however,about the specific defects in collagenmetabolisme in patiënts with POP,

in order to -hopefully one day- stimulate regeneration.
The collagen metabolism can be investigated by measuring the production and breakdown of collagen. Also the type of collagen can be qualified and the quality
of the fibroblasts, responsible for the production of collagen, can be investigated.
According to the present state of science, there is a decrease in collagen production and an increase in breakdown of collagen in patients with POP.
Future research should be based on the following questions.

· To determine whether collagen metabolism and collagen quality are affected in patients with POP;
· To determine whether there is a causal relationship between POP and collagen metabolism;
· To determine whether POP fibroblasts have an intrinsic defective collagen metabolism, and if so, whether AT-MSCs can be used as an alternative source of cells to be used for pelvic floor regeneration.

Study objective

To investigate the collagen metabolism in pelvic floor tissue, pelvic floor-derived fibroblasts, and adipose tissue stem cells in patients with and without pelvic organ prolapse (POP)

Study design

Prospective observational controlled study.

o The collagen metabolism of vaginal tissue will be compared in patients with and without POP.
o In POP patients the collagen metabolism in vaginal tissue will be compared according to the biopsy site: prolapse versus non prolapse.
o The collagen production of the vaginal fibroblast will be compared with adipose tissue derived stem cells (AT-MSC) from the same patient, that are stimulated to produce collagen. This is done both in POP- and non-POP patients.

Study burden and risks

During standard surgery (prolapse repair, hysterectomy) full thickness vaginal tissue is attached to the the surgical specimen (uterus). This tissue from the proximal vagina, measuring 0.5x4 cm is harvested In prolapse patients the strip of the full thickness vagina that is * according to standard procedure -- excised from the prolapse site is examined as well. No additional procedure is performed to collect the vaginal tissue. Ten cc of the periperitoneal adipose tissue will be resected and transported to the department of pathology for cultivation of adipose tissue-derived stem cells (AT-MSC). This space is

already open and easy accessible after removing the uterine specimen. There are no additional risks for the patients participating. Patients have no direct benefits from this investigation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Women with POP undergoing vaginal hysterectomy with anterior and/or posterior repair, 35-75 years of age
- Women without POP undergoing abdominal or vaginal hysterectomy, 35-75 years of age

Exclusion criteria

- No informed consent
- Gynaecologic oncologic disease
- Chronic inflammatory diseases (RA) of chronic infections (HIV, hepatitis)
- Minors or incapacitated adults

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2007
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	NL17851.029.07