The role of collagen genetic discrepancies in development of pelvic organ prolapse in women

Submission date 13/01/2018	Recruitment status No longer recruiting	Prospectively registered		
		☐ Protocol		
Registration date 22/01/2018	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 10/10/2022	Condition category Urological and Genital Diseases	Individual participant data		

Plain English summary of protocol

Background and study aims

Pelvic organ prolapse can be both hereditary (born with it) and acquired. It occurs when the pelvic organ like the bladder drops from its normal place and pushes against the vagina walls. During last decade, the role of genetics in POP becomes profoundly obvious. Scandinavian twin studies have shown that there is a high consistency for pelvic disorders and that genetic factors are reaching up to 40%. Collagen is playing a major role in pelvic floor supportive structures. Connective tissues contain of type I collagen (COL1A1), giving strength to the ligaments due to the length and thickness of the fibers, and type III collagen (COL3A1), an increased amount of which is associated with a decrease in the mechanical strength of the connective tissue. The role of single nucleotide polymorphism (SNP) of the COL1A1 or COL3A1 or COL18A1 genes remain controversial. Some studies and meta-analysis found a strict correlation between these genetic defects and POP; other investigators did not confirm it. The aim of the study is to investigate the role of these SNPs in women suffering pelvic floor prolapse and women without pelvic disorders.

Who can participate?

Women aged 18 and older who have pelvic organ prolapse and women without it.

What does the study involve?

Participants are giving a saliva sample in order to perform a genetic test. The medical history is collected and filed; pelvic floor physical exam will be done. The saliva samples are analyzed for single nucleotide polymorphisms COL3A1 (rs1800255, rs1801184, rs111929073); in COL1A1 (rs1800012); in COL18A1 (rs2236479).

What are the possible benefits and risks of participating?

The benefit for participants would be to have information about genetic collagen related risk factors for connective tissue diseases. There are no anticipated disadvantages or risks to participants in taking part in this study. Whichever group they are allocated to, the tests and assessments are performed by competent and trained clinicians.

Where is the study run from?

This study is being run by the Moscow State University of Medicine and Dentistry and takes place in Urology Department in the Moscow City Hospital (Russia).

When is the study starting and how long is it expected to run for? September 2016 to September 2018

Who is funding the study? Ministry of Health of Russian Federation (Russia)

Who is the main contact? Dr George Kasyan

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

05/2016

Study information

Scientific Title

Single nucleotide polymorphisms in type 1 and 3 collagens in women suffering pelvic organ prolapse

Acronym

SNPs in COL1 and COL3 for Pelvic organ prolapse

Study objectives

The single nucleotide polymorphisms in collagen type 1 alpha 1 or type 3 alpha 1 genes may play a role in development of pelvic organ prolapse in women.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Board of Moscow State University of Medicine and Dentistry, 01/06/2016, ref: # 05-17

Study design

Prospective case-control study that included women with pelvic organ prolapse and the group of control

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Pelvic organ prolapse has a mixed etiology – hereditary and acquired. Collagen is playing a major role in pelvic floor supportive structures. The role of single nucleotide polymorphism of the collagen genes remain controversial. This inconsistency has resulted in the current study in which several polymorphisms in collagen in saliva samples of women will be investigated.

Interventions

This is cross sectional case-control study evaluating the prevalence of single nucleotide polymorphism (SNP) in collagen type 3 alpha 1 chain (COL3A1), collagen type 1 alpha 1 chain (COL1A1) and collagen type 18 alpha 1 chain (COL18A1) genes in patients with pelvic organ prolapse or in control group.

Patient information are extracted from the database of the University Urology Clinic. Patients previously operated for pelvic organ prolapse are contacted via nurse phone call. They are informed about the study and invited for a visit. The control group includes parous women without pelvic organ prolapse.

During the screening visit, participant information and informed consent are provided to women. During the first visit, participants sign informed consent and provide a saliva sample for genetic investigations. The results of the tests are sent to the participants via emails.

Intervention Type

Biological/Vaccine

Primary outcome(s)

Single nucleotide polymorphisms in COL3A1 is investigated using Sanger gene sequencing method.

Key secondary outcome(s))

- 1. Single nucleotide polymorphisms in COL1A1 gene is measured using Sanger gene sequencing method
- 2. Single nucleotide polymorphisms in COL 18A gene is measured using Sanger gene sequencing method

Completion date

01/09/2018

Eligibility

Key inclusion criteria

- 1. Adult women suffering from pelvic organ prolapse and healthy women as controls
- 2. Aged 18 and older

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

Hereditary diseases with a known increased risk of POP, such as Marfan or Ehlers-Danlos syndrome and previous surgeries for POP for the control group

Date of first enrolment

01/01/2017

Date of final enrolment

01/06/2018

Locations

Countries of recruitment

Russian Federation

Study participating centre

Urology Department of Moscow State University of Medicine and Dentistry

Vucheticha 21 Moscow Russian Federation 127206

Sponsor information

Organisation

Ministry of Health of Russian Federation

ROR

https://ror.org/01p8ehb87

Funder(s)

Funder type

Research organisation

Funder Name

Russian Academy of Medical Sciences

Alternative Name(s)

RAMS

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Russian Federation

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Investigators: George Kasyan, Dmitry Vishnevsky at study contact address: urodep@msmsu.ru, tel/fax +7 499 760 75 89

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/08/2018	06/09/2019	Yes	No
Results article		01/01/2021	10/10/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes