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

Submission date	Recruitment status
13/01/2018	No longer recruiting
Registration date	**Overall study status**
22/01/2018	Completed
Last Edited	**Condition category**
10/10/2022	Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Prof George Kasyan

ORCID ID
http://orcid.org/0000-0001-7919-2217

Contact details
Vucheticha 21
Moscow
Saint Helena, Ascension and Tristan da Cunha
126209

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures
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

Overall study start date
15/09/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
250

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

Sponsor details
Rakhmanov Pereulok 3
Moscow
Russian Federation
127994
+7 4956272400
info@rosminzdrav.ru

Sponsor type
Government

Website
rosminzdrav.ru

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal. All additional documents are available in Russian in the study file. Not available in web format, please use the contact details below to request a patient information sheet.

Intention to publish date
01/06/2019

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