ISRCTN48651822 https://doi.org/10.1186/ISRCTN48651822

Examining and measuring the pelvic veins on transvaginal ultrasound

Submission date
13/07/2020

Recruitment status
No longer recruiting

Registration date
20/07/2020

Overall study status
Completed

Last Edited
07/08/2020

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Pelvic pain is a common presenting symptom to the gynaecology clinic and can have a negative impact on the overall quality of life. Pelvic venous congestion is thought to be a potential cause of pelvic pain. This involves dilatation of the pelvic veins. The uterine veins are large vessels in the pelvis that supply the uterus and ovaries, and can be seen on transvaginal ultrasound. Previous studies have demonstrated that dilatation of these veins can lead to pelvic pain but there have been no studies that look at what the normal diameter of the uterine vein is and what other factors can cause them to dilate. The main aim of our study is to measure the uterine veins and see what can lead to their dilatation. The second aim is to see if it is linked to pelvic pain and other common gynaecological symptoms.

Who can participate?
We are planning to recruit women who are referred to our gynaecological outpatient department for ultrasound scans.

What does the study involve?
In all women, in addition to the standard examination of the pelvic organs, we will examine the pelvic veins and take measurements of the diameter. This will not impact or change their care or management.

What are the possible benefits and risks of participating?
The benefits of participating are that dilated uterine veins may trigger symptoms that prompt women to be referred to gynaecology clinics. By examining the uterine veins, we will be able to see if they contribute to common symptoms such as pelvic pain, heavy/irregular bleeding. This will then allow clinicians to offer appropriate treatment. As the examination is part of the routine assessment, there are no additional risks.

Where is the study run from?
Department of Obstetrics and Gynaecology, University College Hospital, UK.

When is the study starting and how long is it expected to run for?
April 2015 to December 2016

Who is funding the study?
University College London, UK.

Who is the main contact?
Ms Tejal Amin
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
156669

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
14/WM/1266, IRAS 156669

Study information

Scientific Title
Assessment of the uterine venous plexus

Study objectives
The uterine pelvic venous plexus can be examined in all women and will differ depending on demographics and presence of pathology

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/12/2014, West Midlands-Solihull HRA REC (Education Centre, Solihull Hospital, Lode Lane, Solihull, B91 2JL, UK; +44 (0)2071048104; NRESCommittee.WestMidlands-Solihull@nhs.net), ref: 14/WM/1266

Study design
Observational cross sectional

Primary study design
Observational

Secondary study design
Cross sectional 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 pain

Interventions
Women who are referred to the gynaecology clinic all have a pelvic ultrasound (transvaginal if tolerated) as part of their routine clinical appointment. Before their scan, they will be asked if their information can be used as part of the study looking at pelvic veins, which is also part of the ultrasound examination. If they agree, they are asked to sign a consent form before the examination. The ultrasound examination usually takes 5-15 minutes, depending on complexity of the findings. The women will be managed depending on their presenting symptoms and ultrasound findings. The measurements of the pelvic veins are an observation and do not affect or contribute to the overall management of the woman. Women will have follow up appointments if the scan or presenting symptoms require further monitoring.

Intervention Type
Procedure/Surgery

Primary outcome measure
1.Diameter of pelvic vein measured during transvaginal ultrasound. The diameter is measured from a frozen image of the vein on the ultrasound machine
2. Pain is measured using the visual analogue score (VAS) at the initial appointment

Secondary outcome measures

Measured at the initial appointment
1. Proportion of women with normal pelvic organs measured using transvaginal ultrasound
2. Proportion of women with evidence of uterine/ovarian pathology measured using transvaginal ultrasound
3. Proportion of women with pelvic pain and/or heavy periods presenting to the gynaecology clinic measured using using the pictorial blood assessment chart (PBAC)

Overall study start date
01/01/2015

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Age > 18 years
2. Ability to undergo a transvaginal ultrasound scan
3. No previous history of hysterectomy
4. Sign written consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
1,500

Total final enrolment
1500

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/08/2015

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College Hospital
Department of Obstetrics and Gynaecology
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Sponsor information

Organisation
University College London

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Sponsor type
University/education

Website
http://www.ucl.ac.uk

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
University/education

Funder Name
University College London

Alternative Name(s)
University College London in United Kingdom, Collegium Universitatis Londinensis, UCL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We are intending to publish the study in an international peer reviewed journal

Intention to publish date
13/07/2020

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v3	14/10/2018	07/08/2020	No	No
HRA research summary			28/06/2023	No	No