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How common are pelvic blood clots in women visiting a gynaecology clinic?

Submission date
15/06/2019

Recruitment status
No longer recruiting

Registration date
25/06/2019

Overall study status
Completed

Last Edited
09/09/2021

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Clots in the veins are an important health problem. Recent studies have shown that the proportion of women attending for a gynaecological ultrasound scan have evidence of asymptomatic clots in their pelvic veins. This is a new finding and the significance is unknown. The main aim of our study is to see how common these asymptomatic clots are in women attending gynaecological outpatient clinics. We also plan to look at what happens to them over time, how and why they develop.

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 stranded examination of the pelvic organs, we will examine the pelvic veins and look for the signs of clots. Those with evidence of blood clots in the pelvic veins will be offered a blood test to check their clotting. Women with abnormal results will then be referred to haematologist (doctors that specialise in blood clotting disorders). Those with normal blood results will be followed up at one, three, and six months following the initial diagnosis or until the clot has resolved on the scan. Women with persistent clots after six months of follow up will also be offered haematological assessment and advice.

What are the possible benefits and risks of participating?
The diagnosis of pelvic vein thrombosis will trigger more detailed investigations including blood tests to identify women who are at risk of developing blood clots in other parts of the body. This would help us to offer them preventative measures to reduce their risk of developing potentially serious complications such as blood clots travelling to the lungs and causing problems with circulation and breathing. The possible risks are that the diagnosis of a uterine vein thrombus may cause anxiety and repeated tests to see whether they have cleared naturally or following the treatment.

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 Davor Jurkovic
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
14/WM/1266

Study information

Scientific Title
The prevalence of incidental uterine venous plexus thrombosis in women attending a gynaecology clinic: A prospective study

Study objectives
We hypothesise that uterine vein thrombosis is common

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; NRESCommittee.WestMidlands-Solihull@nhs.net; 02071048104), ref: 14/WM/1266

Study design
Observational cross-sectional study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Deep vein thrombosis

Interventions
All women underwent a transvaginal ultrasound examination by a single operator. All women who were diagnosed with pelvic vein thrombosis underwent a thrombophilia screen and bilateral lower limb venous duplex scanning.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Prevalence of uterine venous plexus thrombosis measured by observation of a transvaginal ultrasound examination

Key secondary outcome(s))
1. Proportion of women with uterine venous plexus thrombosis with positive thrombophilia screen measured using blood test
2. Proportion of women with uterine venous plexus thrombosis with concomitant leg deep vein thrombosis measured using venous duplex scanning

Completion date
31/12/2016

Eligibility

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

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
1298

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/04/2015

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Obstetrics and Gynaecology
University College Hospital
250 Euston Road
London
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Sponsor information

Organisation
Joint Research Office

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

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?
Results article		11/08/2020	09/09/2021	Yes	No
Results article		26/07/2021	09/09/2021	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes