

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

<b>Submission date</b> 15/06/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/06/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/09/2021	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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 standard 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

**Contact name**  
Ms Davor Jurkovic

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## Additional identifiers

**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

## **Primary study design**

Observational

## **Study design**

Observational cross-sectional study

## **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

United Kingdom

NW1 6BU

## **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?
<a href="#">Results article</a>		11/08/2020	09/09/2021	Yes	No
<a href="#">Results article</a>		26/07/2021	09/09/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No