

Trans-venous occlusion of pelvic vein incompetence

Submission date 14/10/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 14/10/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/04/2023	Condition category Pregnancy and Childbirth	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Chronic pelvic pain (CPP) in women is where pain is felt in the pelvic region (the area below the belly button and between the hips) for at least 6 months. There are many possible causes, however 15-20% of CPP is thought to be due to ovarian vein reflux. The ovaries are an important part of the reproductive system and require a good supply of oxygen rich blood. The ovarian veins are the veins which carry blood away from the ovaries when the oxygen has been used up. A healthy vein is able to carry blood back to the heart (against gravity), and contains valves which stop the blood from flowing back down (reflux). Ovarian vein incompetence happens when the ovarian veins are dilated (widened). This means that the veins are less elastic and so the valves are less effective, causing reflux and blood pooling. This causes a build-up of pressure which can be very painful and uncomfortable. In men, testicular vein incompetence is treated by blocking the affected veins with foam and small metal coils. This is not currently an option available for women with ovarian vein incompetence however. The aim of this study is to look at women who have CPP to find out how many are experiencing pain due to ovarian vein incompetence. The study will then find out if blocking veins with metal coils is an effective treatment option in women with CPP caused by ovarian vein incompetence.

Who can participate?

Women aged between 18 and 54 who have been suffering from pelvic pain for more than 6 months.

What does the study involve?

All participants undergo a special type of scan where a probe is placed in the vagina and an ultrasound image produced, showing the blood flow within the pelvic veins. Women who show pelvic vein incompetence (blood flowing in the wrong direction), continue with the study and have a more complex scan. In the scanning procedure, a thin guide wire is inserted into the jugular vein in the neck, and then guided down to the ovarian veins to place a thin tube (catheter) into them. A special dye is injected through the catheter which shows the direction the blood is flowing in during a scan. All participants are given the scan, however half the women are randomly allocated to have the damaged veins blocked by inserting tiny metal devices and a foam substance into them. All women are asked to complete questionnaires about any pain they have experienced at 1 week, 3 months, 6 months and 12 months after the procedure.

What are the possible benefits and risks of participating?

The benefits of taking part are that the treatment may help to improve the symptoms of Chronic Pelvic Pain Syndrome for that individual. The procedure itself carries a small risk of bleeding and bruising in the neck, pain, and damage to some of the other blood vessels.

Where is the study run from?

Wythenshawe Hospital (UK)

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

September 2015 to September 2018

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Miss Rae Larmour

Contact information

Type(s)

Public

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Additional identifiers

Protocol serial number

19595

Study information

Scientific Title

Transvenous occlusion of incompetent pelvic veins as a treatment for chronic pelvic pain in women: A randomised control trial

Study objectives

Null hypothesis:

Pelvic vein occlusion has no effect on symptoms of chronic pelvic pain in women with refluxing pelvic veins.

Primary hypothesis:

1. Does treatment of PVI by trans-venous occlusion improve symptoms of CPP assessed using the validated SF-MPQ?

Secondary hypotheses:

1. Does treatment of PVI by trans-venous occlusion improve health status measured by the EuroQol (EQ-5D-3 level) in women with CPP?

2. What are the NHS costs of treatment over six months in both treatment groups?

3. What are the key drivers of the relative cost-effectiveness of coil occlusion compared with no treatment for women with PVI?

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee North West - Greater Manchester East, 17/06/2015, ref 15/NW/0360

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Screening

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Reproductive health and childbirth; Subtopic: Reproductive Health and Childb (all Subtopics); Disease: Reproductive Health & Childbirth

Interventions

Participants are randomly allocated to one of two groups. The participant, researchers and responsible Gynaecologist are blinded to the group allocation.

Control Group:

Control participants will receive a single event of reflux venography. This is initiated by

catheterising the right jugular vein with the patient in a supine position under local anaesthesia. The jugular approach is taken as it provides better access to the right ovarian vein. A guidewire is advanced into the inferior vena cava adjacent to the renal veins. The left ovarian vein is cannulated first and reflux venography performed with the patient semi-erect by tilting the table head up.

Incompetence is defined as sustained reflux of greater than 0.5 seconds. Once Pelvic Vein Incompetence is confirmed by reflux venography, allocation to the Venography only arm of the trial is determined by on-line randomisation line. Randomisation is stratified for the vessels identified as incompetent on earlier Trans-vaginal ultrasound scan.

Intervention Group:

Reflux Venography is performed as described above. Allocation to the intervention group is determined by on-line randomisation line on confirmation of Pelvic Vein Incompetence by Reflux Venography. The randomisation is stratified for the vessels identified as incompetent on earlier Trans-vaginal ultrasound scan.

Participants will receive a single trans-venous occlusion procedure including prior reflux venography and post occlusion venography.

Trans-venous occlusion of the incompetent pelvic veins involves the insertion of distal and proximal metallic coils with foam sclerotherapy (Sodium Tetradecyl Sulfate) sandwiched in between. In the internal iliac veins, coil embolization will only be performed to 2nd order branch veins which are incompetent, and not pursued into 3rd or subsequent order branches into the buttock or thigh.

Intervention Type

Other

Primary outcome(s)

Pain is measured using the Short-form McGill Pain Questionnaire which will be completed by participants either online or via post at baseline, 1 week, 3 months, 6 months and 12 months.

Key secondary outcome(s)

Health outcomes are measured using the EuroQol (EQ-5D-3 Level) Questionnaire which will be completed by participants either online or via post at baseline, 1 week, 3 months, 6 months and 12 months.

Completion date

28/09/2018

Eligibility

Key inclusion criteria

1. Women aged between 18- and 54 (inclusive)
2. CPP (constant or intermittent lower abdominal or pelvic pain lasting for more than six months) confirmed by a diagnostic committee including a gynaecologist

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Total final enrolment

60

Key exclusion criteria

1. Pregnant or within 12 months of pregnancy
2. Alternative pathologies that may cause CPP (such as endometriosis, adenomyosis, interstitial cystitis or musculoskeletal pain) as judged by the diagnostic committee
3. Previous hysterectomy
4. Renal failure (eGFR $<30\text{ml/min/1.73m}^2$)
5. Previous cardiovascular event such as myocardial infarction, stroke, angina or history of heart failure
6. A diagnosis of malignancy or treated for malignancy over the last 12 months
7. At increased risk of bleeding such as patients on anticoagulation or history of hereditary bleeding disorders
8. Chronic disability that impairs mobility
9. Unable to give informed consent

Date of first enrolment

27/07/2015

Date of final enrolment

09/10/2017

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

University Hospital of South Manchester

Southmoor Road

Wythenshawe

Manchester

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Study participating centre
Stepping Hill Hospital
Poplar Grove
Hazel Grove
Stockport
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SK2 7JE

Study participating centre
Manchester Royal Infirmary
Oxford Road
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Sponsor information

Organisation
University Hospital of South Manchester NHS Foundation Trust

ROR
<https://ror.org/00he80998>

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/04/2023	25/04/2023	Yes	No
HRA research summary			28/06/2023	No	No