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Trans-
venous occlusion of pelvic vein incompetence

Submission date
14/10/2015

Recruitment status
No longer recruiting

Registration date
14/10/2015

Overall study status
Completed

Last Edited
25/04/2023

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised; Interventional; Design type: Screening

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)

Treatment

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
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 measure
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.

Secondary outcome measures
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.

Overall study start date
19/09/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

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 (eGRF <30ml/min/1.73m2)
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
England

United Kingdom

Study participating centre
University Hospital of South Manchester
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

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

Study participating centre
Manchester Royal Infirmary
Oxford Road
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M13 9WL

Sponsor information

Organisation
University Hospital of South Manchester NHS Foundation Trust

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Wythenshawe Hospital
Southmoor Road
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United Kingdom
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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
30/06/2020

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