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Superficial Endometriosis Treatment trial

Submission date	Recruitment status	[_] Prospectively registered
28/11/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/05/2014	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
02/09/2020	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

This study is looking at a specific type of disease called superficial endometriosis. The endometrial cells lining the inside of the womb respond to hormone changes in the menstrual cycle which make them grow. They are shed, together with blood during a period. Endometriosis occurs when these cells grow in areas such as the ovaries, bladder, bowel, womb muscle or occasionally in scars within the abdomen. They will develop as above under the influence of oestrogen and cause inflammation. This may be little, but may cause pain with a period or intercourse or it may cause scarring around the ovaries, tubes and womb. How endometriosis exactly develops is unknown. The current theory most commonly referred to is called embryological. This means that when patients are being conceived themselves in the womb, something does not go to plan, and cells that were destined to become part of the female reproductive system were misplaced. These cells when stimulated by oestrogen (at puberty and beyond) will develop as described above. Endometriosis is not a cancerous condition. This study is to help identify the best way to treat patients with endometriosis surgically. Currently there is little evidence on the best way to vaporise/remove endometriosis, but one way is using diathermy (electrical energy, causing heat). There are two methods of electrodiathermy (electricity used as a surgical tool to cut or vaporise tissue depending on differing waveforms - Monopolar & Bipolar - used in standard practice already: Monopolar (energy is passed through an instrument to the tissue and passes to a sticker plate placed on the patient to exit) and bipolar (electricity passed through one side of instrument to another to exit). Currently the choice of surgical instrument (treatment tool) is purely down to the surgeons personal preference rather than evidence of better treatment or reduced risk. This study is designed to investigate if either of the methods has a greater impact on the patients pain symptoms in the 8 month follow-up period following surgery.

Who can participate?

Each patient referred for a laparoscopy for pain of suspected endometriosis origin who has not been diagnosed as such previously could opt in. Once the laparoscopy is under way the pelvis will be examined, looking for evidence of endometriosis and if found the patient could then be entered into the study. During the surgery if endometriosis is NOT found then patients do not participate in the study and are informed on waking in recovery.

What does the study involve?

There are no additional treatments/investigational procedures as part of this study, only four

short questionnaires to fill in at differing times. The first questionnaire is given after being consented into the study on the morning of the already planned surgery. Once the laparoscopy is under way the pelvis is examined, looking for evidence of endometriosis. If endometriosis is found and if it is suitable for the treatments involved in the study, patients are entered into the study. They are randomly allocated to either of the two treatment groups and the endometriosis is treated there and then. They are not told what treatment they have received. On waking up in recovery participants are asked to give pain scores again. Participants are seen in clinic to assess the benefit after surgery and a questionnaire is completed. If a further follow-up is required clinically at 8 months post-surgery they are asked again to complete the same questionnaire. If they are discharged before this they are posted a questionnaire to complete with a returnable envelope and paid postage. There are no additional appointments or procedures, nor is there any added risk to the operation.

What are the possible benefits and risks of participating?
The researchers cannot promise a benefit from taking part in the study. However, the results of the study may change the way that superficial endometriosis is treated and potentially lead to improved care in future. There are no additional risks or disadvantages from study involvement. Although some questions may be thought of as personal in nature, and interpreted as a disadvantage, however they are all questions asked in a normal clinical assessment and so are not new/different.

Where is the study run from?
Portsmouth Hospital NHS Trust (UK)

When is the study starting and how long is it expected to run for?
February 2014 to August 2015

Who is funding the study?
Portsmouth Hospital NHS Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PHT/2013/79

Study information

Scientific Title
A randomised, single-blind clinical trial to investigate the effectiveness of bipolar versus monopolar diathermy treatment on pain symptoms for women with newly diagnosed superficial endometriosis: the SET study (Superficial Endometriosis Treatment)

Acronym
SET

Study objectives
Endometriosis is a common condition in women of reproductive age which causes significant pain and morbidity, reduces quality of life, and may necessitate medical interventions of various types over many years. A surgical approach includes the removal of areas of endometriosis using a process called diathermy, which carried out using either a monopolar or bipolar method. However, no conclusive evidence exists to inform surgeons as to which instrument to use within basic diathermy techniques for superficial endometriosis. If the effectiveness of either technique is superior, this would lead to improved post-surgical pain symptoms and quality of life for patients, and potentially reduced costs for the NHS in terms of consequent intervention and admissions.

Null Hypothesis: No difference exists between monopolar diathermy and bipolar diathermy when treating superficial endometriosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee south central Hampshire A, amendment date: 06/05/2014, REC ref: 14/sc /0017, IRAS ID: 123696

Study design
Single-blind (participant) randomized controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Gynaecology - Endometriosis

Interventions
Two study arms: Monopolar and Bipolar diathermy

Monopolar or bipolar diathermy:
Generally surgical treatment involves ablation or excision of endometriotic lesions. Ablation methods vary from use of lasers, and differing techniques of basic diathermy. Diathermy is the use of high frequency electric current to produce heat and it is used to either cut or destroy tissue by producing coagulation. The mains electricity in use in the UK is 50 Hz and produces intense muscle and nerve activation so the electrical frequency used by diathermy is in the range of 300 kHz to 3 MHz so the current has no effect on muscles.

Monopolar diathermy has an electrical return plate that is placed on the patient (usually the thigh), which acts as an indifferent electrode (Figure1.) A current passes between the instrument and the indifferent electrode. As the surface area of the instrument is less than that of the plate, produces a focus point at tip of instrument usually resulting in coagulation or vaporization. Away from the immediate point of contact of the active electrode, the current spreads out, with minimal heating effect produced at indifferent electrode. It shouldnt cause burns under the pad as the current flow per square centimetre of skin will be small. Modern machines test to ensure that the pad is properly applied. Complications include interference with pacemaker function, arcing can occur with metal instruments and implants, superficial burns if use of spirit based skin preparation, diathermy burns under indifferent electrode if plate improperly applied and channeling effects if used on viscus with narrow pedicle.

The effects of diathermy depend on the current intensity and wave-form used. Coagulation is produced by interrupted pulses of current (50-100 per second up to 6,000 volts) in a square wave-form. The aim of this is to desiccate the tissue, but not to vaporise it. It generates lower tissue temperatures than with cutting current. Usually it is applied for < 10% of the time the pedal is operated. It treats bigger volumes of tissue, goes deeper than with cutting and so a coagulating current provides good haemostasis.

Cutting is produced by continuous current at low voltage of 500 1,000 volts. The water in the cells is turned to steam, so the cells vaporise giving a cutting effect. The best effect will occur when the current flows through the smallest tissue volume. There is only vaporising of the tissue

in the immediate vicinity of the instrument. Because the effect is relatively superficial and the tissues are vaporised, not coagulated, there is no great haemostasis.

Bipolar diathermy uses two electrodes combined in one instrument, usually forceps, with a current passing between tips (from the active electrode to the neutral electrode) and not through the patient. Due to this system current does not routinely pass through the patient and associated risk of electrosurgery as described above are much less this with method.

Despite the electrical safety benefits many surgeons prefer the monopolar diathermy as it offers better dissection and control with hence reduced thermal spread, perhaps offering a benefit surgery.

Follow up is for 8 months postoperatively.

Intervention Type
Procedure/Surgery

Primary outcome measure
VAS difference at 4 months post-surgery

Secondary outcome measures
1. VAS difference at 8 months post-surgery.
1.1. Overall VAS (average) changes from baseline at 4 and 8 months post-surgery in combined pain domains (Dyspareunia, chronic pelvic pain, menstrual pain).
1.2. Individual VAS change from baseline at 4 and 8 months post-surgery in separate domains of pain domains (Dyspareunia, chronic pelvic pain, menstrual pain).
2. Health state questionnaire change from baseline at 4 and 8 months post surgery.
3. To assess rates or work related sickness at 4 and 8 months post surgery.
4. To assess rates of pain-related admissions to gynaecology during 8 months of follow-up.
5. To describe adverse events, including surgical complications.

Overall study start date
03/02/2014

Completion date
01/08/2015

Eligibility

Key inclusion criteria
Preoperative
The patient must meet ALL of the following criteria to be considered eligible for the study:
1. Female
2. Aged 18 years and above.
3. Scheduled for diagnostic laparoscopy due to history of pelvic pain (clinical suspicion of endometriosis)
4. Willing and able to give informed consent for participation in the study

Intraoperative
The participant must meet ALL of the following criteria to be considered eligible for the study:
Superficial endometriosis found at laparoscopy, defined by Stage I or II of the revised American Fertility Society rAFS score.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
32

Key exclusion criteria
Preoperative
The patient may not enter the study if ANY of the following apply:
1. Previous diagnosis of endometriosis from previous surgery/assessment
2. If language or competency barriers exist during consenting

Intraoperative
The participant may not enter the study if ANY of the following apply:
1. Position of endometriosis contraindicates use of either diathermy treatment due to risk of complications, e.g. endometriosis vesicle over the ureter

Date of first enrolment
03/02/2014

Date of final enrolment
01/08/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

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Sponsor information

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/009fk3b63

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Portsmouth Hospital NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration