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Helium thermocoagulation versus electrodiathermy for endometriosis

Submission date	Recruitment status	[_] Prospectively registered
11/12/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/12/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/05/2021	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Endometriosis is a condition where cells similar to those within the lining of the womb are found elsewhere in the body. It can be a chronic and painful condition for some women. Around 2 million women in the UK are affected by endometriosis. It is a long-term condition that causes painful or heavy periods and lower abdominal, pelvic or lower back pain. It may also lead to fertility problems.
There is no known cure for endometriosis, although symptoms may be controlled by hormone treatments or painkillers. Women who do not respond may be offered minimally invasive (keyhole) surgery to remove the diseased tissue. This treatment is applied through a special tube called a laparoscope. The standard keyhole procedure to treat this condition is laparoscopic removal or burning of tissue with electrodiathermy (a procedure in which tissue is heated to destroy abnormal cells). This can have side effects such as inadvertent injury to the bowel or the urinary system. Therefore, we aim to test the effectiveness of a relatively new treatment that involves the use of a helium beam thermo-coagulator that potentially has fewer side-effects. This study aims to address this by directly comparing two different keyhole procedures: standard treatment (electrodiathermy) and helium thermal electro-coagulation.

Who can participate?
The study aims to recruit women between 16 years and 50 years with pelvic pain and a clinical diagnosis of mild or moderate endometriosis.

What does the study involve?
Participants will be randomly allocated to one of two groups:
1.Laparoscopic ablation/excision of mild to moderate endometriosis with helium thermal electro-coagulation
2. Laparoscopic ablation/excision of mild to moderate endometriosis with electrodiathermy
The team will assess the differences between the two procedures on the relief of symptoms, complications and quality of life for endometriosis sufferers. We will collect data from the patients before surgery and at 6 weeks, 3 months and 9 months after surgery. The study team will use the data collected to inform patients and doctors of the best choice for endometriosis surgery that has the best symptom relief and fewer complications.

What are the possible benefits and risks of participating?
It is anticipated that this study will contribute to evidence-based practice in the surgical treatment of endometriosis and will thereby allow patients to make a more informed choice of surgical intervention. More specifically, identifying the procedure that brings about superior pain relief will reduce the symptom burden of this condition and allow better targeting of treatment resources. Information on the relative complications (during and after surgery) of the two procedures will permit procedure-related morbidity to be reduced.
The risk to participants is minimal as both groups of patients will receive an intervention that is standard practice and considered to be safe.

Where is the study run from?
University Hospital of North Staffordshire NHS Trust (UK).

When is the study starting and how long is it expected to run for?
The study started in December 2013 and will finish in September 2018

Who is funding the study?
National Institute for Health Research (UK).

Who is the main contact?
Dr Keira Watts
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15332

Study information

Scientific Title
Laparoscopic excision/ablation with a helium thermal coagulator compared with electro-diathermy for the treatment of mild to moderate endometriosis: a randomised controlled trial

Study objectives
We hypothesise that laparoscopic excision/ablation of endometriosis with a helium thermal coagulator is associated with superior symptom relief and reduced morbidity compared with laparoscopic excision of endometriosis with electrodiathermy.

More details can be found at: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=15332

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands Leicester, 03/10/2013, REC number 13/EM/0354

Study design
Randomised controlled interventional treatment trial

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 shee

Health condition(s) or problem(s) studied
Topic: Reproductive Health and Childb; Subtopic: Reproductive Health and Childb (all Subtopics); Disease: Reproductive Health & Childbirth

Interventions
1. Laparoscopic ablation/excision of mild to moderate endometriosis with a helium thermal coagulator
2. Laparoscopic ablation/excision of mild to moderate endometriosis with electrodiathermy

Both arms will have a follow-up schedule of 6 weeks, 3 months and 9 months.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Pelvic Pain - VAS scores; Timepoint(s): 3 months

Secondary outcome measures
Intra-operative and post-operative complication and pregnancy rates in patients with associated subfertility. This is assessed by Quality of Life pre- and post-operatively at all follow-up visits with the Endometriosis Health Profile (EHP) 30.

Overall study start date
02/12/2013

Completion date
30/09/2018

Eligibility

Key inclusion criteria
1. Patients aged between 16 and 50 years with pelvic pain (with or without associated dyspareunia or dysmenorrhea)
2. A clinical diagnosis of mild or moderate endometriosis

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 158; UK Sample Size: 158

Total final enrolment
192

Key exclusion criteria
1. Possibility of gynaecological cancer
2. Advanced endometriosis
3. Pregnancy
4. Unable to give informed consent.
5. Patients currently involved in other endometriosis or pelvic pain research

Date of first enrolment
02/12/2013

Date of final enrolment
01/10/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Unit of Obstetrics and Gynaecology
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Sponsor information

Organisation
University Hospital of North Staffordshire NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name

NIHR Research for Patient Benefit (RfPB) (UK) ; Grant Codes: PB-PG-0212-27072

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2020	07/05/2021	Yes	No
HRA research summary			28/06/2023	No	No