

# Helium thermocoagulation versus electrodiathermy for endometriosis

<b>Submission date</b> 11/12/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/12/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/05/2021	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

## 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

Dr Keira Watts

### Contact details

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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 electrodiathermy 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 sheet

## 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**

Stoke-On-Trent

United Kingdom

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## **Sponsor information**

**Organisation**

University Hospital of North Staffordshire NHS Trust (UK)

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

## **Funder(s)**

**Funder type**

Government

**Funder Name**

## 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?
<a href="#">Results article</a>		01/11/2020	07/05/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No