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Comparing medical management with laparoscopic surgery for the treatment of deep endometriosis

Submission date
03/05/2022

Recruitment status
Stopped

Registration date
10/05/2022

Overall study status
Stopped

Last Edited
03/07/2025

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Endometriosis is a common condition affecting 1 in 10 women, which can cause severe pain. It happens when cells similar to those lining the womb grow outside the womb, generally on surfaces and organs within the pelvic cavity, causing bleeding, scarring and inflammation. Occasionally, rather than growing on or very near the surface, the endometriosis cells can grow deeper into tissues and organs, such as the bowel, bladder and the vagina, causing a painful condition which is called deep endometriosis. The aim of this study is to compare medical (hormonal) management versus surgery for deep endometriosis.

Who can participate?
Pre-menopausal women aged between 18 and 49 years old seeking treatment for deep endometriosis related pain

What does the study involve?
Women who decide to take part will be randomly assigned (using a computer) to join one of the study groups either to receive hormonal medical treatment (for 18 months) or laparoscopic surgery. When they join the study they will be asked to complete a questionnaire about their pain and quality of life. At 3, 12 and 18 months, they will be asked to complete additional questionnaires about their pain, and endometriosis symptoms. Women in either group can also receive additional pain relief and if the medical treatment is not working they can opt to have surgery.

What are the possible benefits and risks of participating?
Women will receive the same health care from their doctors whether or not they choose to participate in the study. By taking part, they will be directly helping the researchers to find the best treatment for women with deep endometriosis and helping women who have this condition in the future. The results of the study will also help plan effective services offered to women with deep endometriosis. The researchers do not think that there are any possible disadvantages to taking part in this study. Whichever treatment they are allocated, this will be performed by a competent and trained clinician. There are risks associated with all procedures,

anaesthetics and medications. Steps are always taken to ensure that these risks are minimised. As part of routine care, they will be well informed of potential risks.

Where is the study run from?
Aberdeen University (UK)

When is the study starting and how long is it expected to run for?
January 2021 to April 2025

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

Who is the main contact?
Dr Lynda Constable
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Study website
https://w3.abdn.ac.uk/hsru/DIAMOND/Public/Public/index.cshtml

Contact information

Type(s)
Principal Investigator

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
298771

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52443, IRAS 298771

Study information

Scientific Title
Deep infiltrating endometriosis: management by medical treatment versus early surgery: DIAMOND

Acronym
DIAMOND

Study objectives
1. Determine whether medical (hormonal) treatment is as effective as laparoscopic surgical treatment for women with deep endometriosis
2. Assess the cost-effectiveness of medical (hormonal) treatment with laparoscopic surgery

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/01/2022, West of Scotland REC 4 (Research Ethics, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 314 0213; WoSREC4@ggc.scot.nhs.uk), ref: 21/WS/0136

Study design
Randomized controlled trial; Design type: Treatment, Surgery, Qualitative

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
https://w3.abdn.ac.uk/hsru/DIAMOND/Public/Public/index.cshtml

Health condition(s) or problem(s) studied
Deep infiltrating endometriosis

Interventions
Women with deep endometriosis will be invited to take part. Women with deep endometriosis will be referred by their GP to specialist endometriosis centres and will be invited to take part in DIAMOND by the endometriosis team.

Potentially eligible women will be given information about the study. Those who are interested in taking part will be asked to sign a consent form. They can do this at their outpatient appointment or at home after the appointment. Women will have the option to complete either a paper consent form or complete the consent form electronically.

Consent forms that are returned by post are checked, signed and dated with the date of receipt by someone who is listed on the delegation log with appropriate delegated responsibilities.

Participant completed e-consent forms will be checked, and electronically counter-signed by someone listed on the delegation log with appropriate delegated responsibilities.

The countersignature will only be recorded after a discussion has taken place with the participant about the study and any questions have been answered. Only once both patient and clinician signatures are present will informed consent be considered to have been obtained.

Any e-consent obtained will be verbally confirmed by the site at any future communication.

Participants will be sent a copy of the paper consent or e-consent form for their own records and a copy will be retained in the investigator site file and TMF.

After a woman consents to the DIAMOND study, baseline data will be collected, and women will be asked to complete a questionnaire about their condition and their quality of life. Then, women will be randomised to either medical (hormonal) treatment or surgery.

There are different types of medical (hormonal) treatment available - including the combined contraceptive pill/patch (COCP), progestogen only preparations (oral tablets, depot injections, subcutaneous implants or intrauterine systems), danazol and gonadotrophin releasing hormone (GnRH) analogues with add back hormone replacement therapy (HRT). For women randomised to medical (hormonal) treatment, the choice of hormonal treatment will be made following

discussion between the woman and the endometriosis team. The hormonal treatment will be prescribed by the endometriosis team or the woman's GP. Treatments that need to be administered (for example depot injections, implants) can be administered in secondary care by the endometriosis team or in primary care.

Women who are randomised to laparoscopic surgery will be added to the waiting list for surgery. A laparoscopic approach will be used, but the choice of energy modalities and the need for concomitant hysterectomy and/or oophorectomy will be left to the discretion of the surgeon in consultation with their patient.

Women in both randomised arms can be offered analgesics or neuromodulators for additional pain relief. Women in the surgical arm can also be offered hormonal treatment if felt this would be beneficial to the patient's well being. Women in the medical treatment arm may be referred for surgery.

The researchers will ask women to complete questionnaires at 12 weeks and then at 12 and 18 months to collect information on pain, quality of life, compliance with treatment and any side effects. They will collect this follow-up information for 18 months from all women in the study, whether or not they receive their randomised treatment.

There is a qualitative sub-study:

The first component of this involves audio-recording consultations and will only be implemented at trial sites where recruitment is problematic. In sites where it is activated, women will receive information about this in advance of the consultation and will be asked to give verbal agreement for the recording at the start of their consultation.

The second component of this will involve interviews with women and study teams. Potential participants will be provided with information and if they agree to take part, verbal agreement for the interview will be sought at the beginning of the interview.

The qualitative sub-study will identify challenges relating to the design and conduct of the trial, particularly around recruitment.

Intervention Type
Mixed

Primary outcome measure
Primary clinical outcome:
Endometriosis-associated pain measured using the pain domain of the condition-specific Endometriosis Health Profile-30 (EHP-30) at 18 months post-randomisation

Primary economic outcome:
Incremental cost per quality-adjusted life-year (QALY) gained from a health service perspective, measured using self-completed questionnaires and case note reviews at 18 months post-randomisation

Secondary outcome measures
Patient-reported outcomes measured using self-completed questionnaires at 3, 12, 18 months post-randomisation, unless stated otherwise:
1. Satisfaction with treatment measured on a six-point scale from ‘totally satisfied’ to ‘totally dissatisfied’

2. Endometriosis-associated pain measured using the pain domain of EHP-30
3. Generic and condition-specific quality of life measured using EQ-5D and EHP-30
4. Need for further medical treatment and/or gynaecological surgery measured using self-completed questionnaires and case note review at 18 months post-randomisation
5. Serious adverse events and major surgical complications assessed using self-completed questionnaires, site-completed case report forms and case note reviews at 18 months post-randomisation
6. Discontinuation of randomised treatment assessed using self-completed questionnaires and case note review at 18 months post-randomisation
7. Occupational outcomes assessed using the Work Productivity and Activity Impairment Questionnaire: General Health V2.0
8. Sexual health measured using the EHP-30 sexual health module
9. Pregnancy measured using patient self-report and case note review at 18 months

Overall study start date
01/01/2021

Completion date
30/04/2025

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Women aged 18–49 years old seeking treatment for pain
2. Laparoscopically confirmed deep endometriosis +/- radiological imaging
3. Suitable for either medical or surgical management
4. Able and willing to give informed consent to participate and to participate in study procedures

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
49 Years

Sex
Female

Target number of participants
Planned Sample Size: 400; UK Sample Size: 400

Total final enrolment

Key exclusion criteria
1. Unfit for laparoscopic surgery
2. Have used or currently using GnRH analogues without satisfactory relief of pain symptoms
3. Previous bilateral oophorectomy
4. Previous surgery for deep endometriosis
5. Planning to conceive in the next 18 months
6. Confirmed bowel stenosis
7. Hydronephrosis or hydroureter caused by ureteric stenosis
8. Endometrioma >5 cm in diameter
9. Women with preference for medical treatment or surgical treatment
10. Current pregnancy or breastfeeding

Date of first enrolment
01/06/2022

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Road
Aberdeen
United Kingdom
AB25 2ZN

Study participating centre
Birmingham Women's Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2TG

Study participating centre

Royal Derby Hospital (nuh)
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Royal Cornwall Hospital (treliske)
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
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BS10 5NB

Study participating centre
University College London Hospital
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
Royal Infirmary of Edinburgh at Little France
51 Little France Crescent
Old Dalkeith Road
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Sponsor information

Organisation

NHS Grampian

Sponsor details
Foresterhill House Annexe
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AB25 2ZB
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Sponsor type
Hospital/treatment centre

Website
http://www.nhsgrampian.org/nhsgrampian/gra_display_home_2015.jsp?p_applic=CCC&p_service=Content.show&pContentID=9298&

ROR
https://ror.org/00ma0mg56

Organisation
University of Aberdeen

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Sponsor type
University/education

Website
http://www.abdn.ac.uk/

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
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/04/2026

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

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?
HRA research summary			28/06/2023	No	No
Plain English results			03/07/2025	No	Yes