ISRCTN27244948 https://doi.org/10.1186/ISRCTN27244948

ESPriT2 – a multicentre clinical trial to determine whether surgical removal of superficial peritoneal endometriosis improves pain symptoms and quality of life

Submission date
24/02/2021

Recruitment status
No longer recruiting

Registration date
06/04/2021

Overall study status
Ongoing

Last Edited
06/11/2024

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Endometriosis is a chronic, incurable condition that affects about 10% of women of reproductive age. It is defined as a growth of cells similar to the womb lining outside of the womb in the pelvis, and is associated with chronic pelvic pain,excessive period pain, pain with sexual intercourse and difficulties in getting pregnant. If the disease is found only on the lining of the pelvis it is known as “superficial peritoneal endometriosis” and is usually treated during a laparoscopic surgery by cutting out (excision) or burning off (ablation). However, many women do not find improvement in their symptoms after the surgery and can have complications from the procedure. The aim of this study is to determine if removal of the superficial peritoneal endometriosis improves pain symptoms and quality of life, which method of removal (excision or ablation) is more effective or if surgical removal is of no benefit to the patients and can potentially cause harm.

Who can participate?
Women who are attending gynaecology departments with pelvic pain who have not previously had a diagnosis of endometriosis via laparoscopy.

What does the study involve?
Patients who consent to the trial will be randomised during the surgery, if superficial endometriosis is found, to either having the endometriosis removed or not. Follow-up will be at 30 days, 3, 6 months and 12 month post-operatively. We will also carry out a data linkage follow-up of up to 5 years.

What are the possible benefits and risks of participating?
Participants may or may not get a direct benefit from taking part in this trial. This trial will generate information to allow women with suspected endometriosis and gynaecologists to make an informed choice whether to immediately remove endometriosis when a diagnostic laparoscopy identifies superficial peritoneal endometriosis alone. If the trial shows that removal

of superficial peritoneal endometriosis does not help, or makes symptoms worse, this would mean that women could choose to not have it removed or avoid a diagnostic laparoscopy altogether. Women could then opt for early pain management with painkillers, hormones and drugs that work on the nerves in the pelvis.

Where is the study run from?
The trial is being run by Professor Andrew Horne's trial management group in the University of Edinburgh, with database and statistical support from Edinburgh Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
January 2021 to June 2026

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

Who is the main contact?
Ann Doust (ann.doust@ed.ac.uk or ETMT@ed.ac.uk)

Study website
https://www.ed.ac.uk/centre-reproductive-health/ESPriT2 (website under construction)

Contact information

Type(s)
Public

Contact name
Mrs Ann Doust

ORCID ID
http://orcid.org/0000-0001-8726-7186

Contact details
Second Floor Simpson Centre for Reproductive Health
University of Edinburgh
Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA
07810643488
ann.doust@ed.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
291525

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 291525

Study information

Scientific Title
ESPriT2 - A multi-centre randomised controlled trial to determine the effectiveness of laparoscopic removal of isolated superficial peritoneal endometriosis for the management of chronic pelvic pain in women

Acronym
ESPriT2

Study objectives
Laparoscopic removal of isolated superficial peritoneal endometriosis is more effective than diagnostic laparoscopy to manage endometriosis-associated pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/01/2021, East of Scotland Research Ethics Service (Tayside Medical Science Centre, Ninewells Hospital, Dundee, DD1 9SY, UK; +44 (0)1382 383848; tay.eosres@nhs.scot), ref: 20/ES/0127

Study design
A multi-centre participant-blind parallel-group randomised controlled clinical and cost effectiveness trial with internal pilot

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
https://www.ed.ac.uk/centre-reproductive-health/ESPriT2 (website under construction)

Health condition(s) or problem(s) studied
Women with isolated superficial peritoneal endometriosis

Interventions
Participants will be randomised at time of laparoscopy if superficial peritoneal endometriosis only is found. Randomisation will be to either remove the lesions by excision/ablation/both (depending on operating surgeon's preference) or to diagnostic laparoscopy alone.
Randomisation is via an on-line database and will take place during laparoscopy once eligibility has been confirmed.
Follow-up will be at 30 days, 3, 6 months and 12 month post-operatively. We will also carry out a data linkage follow-up of up to 5 years.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain at 12 months post randomisation as defined by the 'pain domain' of the EHP-30 questionnaire

Secondary outcome measures
1. Time off work and presenteeism defined by the WPAIQ at 12 months
2. Need for hormonal medication for endometriosis related symptoms at 3, 6 and 12 months
3. Need for analgesics for endometriosis related symptoms at 3, 6 and 12 months
4. Pain domain of the EHP-30 at 3 and 6 months
5. Total score of EHP-30 at 3, 6 and 12 months
6. Fatigue symptoms defined by the BFI at 12 months
7. Neuropathic pain symptoms defined by PainDETECT™ at 12 months
8. Urinary symptoms defined by PUF 12 months
9. Irritable bowel symptoms defined by the ROME IV criteria at 12 months
10. Pain catastrophizing defined by PCQ at 12 months
11. Fibromyalgia defined by FS at 12 months
12. Specific patient reported symptoms defined by MYMOP2
13. Post operative pain and analgesic requirements by patient reported diary
14. Length of hospital stay measured using patient records
15. Surgical complications at 30 days measured using patient records
16. Adverse events related to surgery at 30 days measured using patient records
17. Need for further surgery for endometriosis related symptoms at 12 months measured using patient records
18. Pregnancy events at 3, 6 and 12 months

Economic Outcomes
19. Quality of life defined by EQ5D-5L at 3, 6, and 12 months
20. General wellbeing defined by ICECAP-A at 3, 6 and 12 months
21. Costs and resource use at 3, 6 and 12 months (primary and secondary care) collected via a telephone call and completion of a data collection form
22. Impacts on employment, caregiving, and other usual activities (e.g. education) collected via a telephone call and completion of a data collection form

Overall study start date
01/01/2021

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Aged over 16
2. Undergoing laparoscopy for the investigation of chronic pelvic pain
3. In order to be randomised, isolated superficial peritoneal endometriosis (SPE) must be identified at laparoscopy (macroscopically)
4. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Female

Target number of participants
400

Key exclusion criteria
1. Previous surgical diagnosis of endometriosis
2. Pregnant
3. Women who have undergone hysterectomy and or bilateral oophorectomy
4. Deep endometriosis on imaging or at time of laparoscopy
5. Ovarian cyst on imaging that is the indication for surgery
6. Ovarian cyst requiring surgical management at time of laparoscopy
7. Dense adhesions that require surgical management at time of laparoscopy
8. Peritoneal ‘pockets’ only noted at laparoscopy
9. Endometrioma observed at the time of laparoscopy

Date of first enrolment
05/05/2021

Date of final enrolment
28/02/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Royal Infirmary of Edinburgh
NHS Lothian
51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Aberdeen Infirmary
NHS Grampian
Foresterhill
Aberdeen
United Kingdom
AB25 2ZN

Study participating centre
University Hospital Crosshouse
NHS Ayrshire and Arran
Crosshouse
Kilmarnock
United Kingdom
KA2 0BE

Study participating centre
Victoria Hospital
NHS Fife
Kirkcaldy
United Kingdom
KY2 5AH

Study participating centre
Forth Valley Hospital
NHS Forth Valley
Stirling Road
Larbet
United Kingdom
FK5 5WR

Study participating centre
City Hospital
SWB NHS Trust
Dudley Road
Birmingham
United Kingdom
B18 7QH

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

Study participating centre
Princess of Wales Hospital
Cwm Taf Morgannwg UHB
Coity Road
Bridgend
United Kingdom
CF31 1RQ

Study participating centre
Burnley General Hospital
East Lancashire NHS Teaching Trust
Casterton Avenue
Burnley
United Kingdom
BB10 2PQ

Study participating centre
Addenbrooke's Hospital
Cambridge University Hospital NHS Foundation Trust
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Countess of Chester Hospital
Countess of Chester Hospital NHS Foundation Trust
Chester
United Kingdom
CH2 1UL

Study participating centre
St Mary's Hospital
Manchester University NHS Foundation Trust
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
North Devon District Hospital
Royal Devon and Exeter NHS Foundation Trust
Raleigh Heights
Barnstaple
United Kingdom
EX31 4JB

Study participating centre
John Radcliffe Hospital
Oxford University Hospitals NHS Foundation Trust
Headley Way
Oxford
United Kingdom
OX3 9DU

Study participating centre
Derriford Hospital
University Hospitals Plymouth NHS Trust
Derriford Road
PLYMOUTH
United Kingdom
PL6 8DH

Study participating centre

University Hospitals Dorset
Longfleet Road
Poole
United Kingdom
BH15 2JB

Study participating centre
Queen Alexandra Hospital
Portsmouth Hospitals University NHS Trust
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Rotherham Hospital
The Rotherham NHS Foundation Trust
Moorgate Road
Rotherham
United Kingdom
S60 2UD

Study participating centre
Royal Cornwall Hosptial
Royal Cornwall Hospitals NHS Trust
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
Princess Anne Hospital
University of Southampton NHS
Coxford Road
Southampton
United Kingdom
SO16 5YA

Study participating centre
Southend University Hospital
Southend University Hospital NHS Foundation Trust

Prittlewell Chase
Westcliff-on-Sea
Southend-on-Sea
United Kingdom
SS0 0RY

Study participating centre
James Cook Hospital
South Tees NHS Trust
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
South Tyneside District Hospital
South Tyneside and Sunderland Foundation Trust
South Shields
United Kingdom
NE34 0PL

Study participating centre
Stoke Mandeville Hospital
Bucks Healthcare NHS Trust
Aylesbury
United Kingdom
HP218AL

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Princess Royal Hospital
Shrewsbury and Telford Hospitals NHS Trust
Telford
United Kingdom
TF1 6TF

Study participating centre
University College London Hospital
University College London Hospitals NHS Foundation Trust
Gynaecology Unit
Lower Ground Floor
EGA Wing
235 Euston Road
London
United Kingdom
NW1 2BU

Study participating centre
Manor Hospital
Walsall Healthcare NHS Trust
Moat Road
Walsall,
United Kingdom
WS2 9PS

Study participating centre
West Middlesex University Hospital
West Middlesex University Hospital, Chelsea and Westminster Hospital NHS Foundation Trust
Twickenham Road
Isleworth
London
United Kingdom
TW7 6AF

Study participating centre
Yeovil District Hospital
Yeovil District Hospital NHS Foundation Trust
Higher Kingston
Yeovil
United Kingdom
TA19 0BE

Sponsor information

Organisation
University of Edinburgh

Sponsor details
ACCORD offices
QMRI
47 Little France Crescent
Edinburgh
Scotland
United Kingdom
EH16 4TJ
+44 (0)131 242 3326
resgov@accord.scot

Sponsor type
University/education

Website
https://www.accord.scot

ROR
https://ror.org/01nrxwf90

Organisation
NHS Lothian

Sponsor details
ACCORD offices
QMRI
47 Little France Crescent
Edinburgh
Scotland
United Kingdom
EH16 4TJ
+44 (0)131 242 3326
resgov@accord.scot

Sponsor type
Hospital/treatment centre

Website
http://www.nhslothian.scot.nhs.uk/Pages/default.aspx

ROR
https://ror.org/03q82t418

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
The primary academic outputs of the ESPriT2 study will include an HTA monograph and a high-impact open access peer-reviewed journal publication. The trial launch and its results at completion will be disseminated nationally through the BSGE via its SCOPE newsletter (published every three months), which is sent out to all members. Presentations and reports will be submitted to UK specialist bodies with the responsibility of guiding clinical practice, policies, research priorities, governance and training in matters related to pathways of management of women with endometriosis. This will include the Royal College of Obstetricians and Gynaecologists (RCOG) and BSGE. The results of the trial will be included in updates of the NICE guidelines and relevant Cochrane reviews, which directly influence practice in the UK and worldwide respectively. In addition, there will also be a project webpage to be hosted on the Endometriosis UK, EAI and Endometriosis.org websites and the University of Edinburgh website. Professor Vincent will ensure relevant members of the pain community are updated and a summary of the trial at its launch and its findings will be disseminated in the newsletter of the IASP Abdominal and Pelvic Pain SIG and additionally communicated to the British Pain Society for communication to all their members who may work in pelvic pain clinics.

Intention to publish date
30/07/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		22/06/2023	23/06/2023	Yes	No
HRA research summary			28/06/2023	No	No