

# ESPrIT2 – a multicentre clinical trial to determine whether surgical removal of superficial peritoneal endometriosis improves pain symptoms and quality of life

<b>Submission date</b> 24/02/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 06/04/2021	<b>Overall study status</b> Ongoing	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 06/11/2024	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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)

## Contact information

### Type(s)

Public

### Contact name

Mrs Ann Doust

### ORCID ID

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

291525

### ClinicalTrials.gov (NCT)

Nil known

**Protocol serial number**

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

**Study type(s)**

Quality of life

**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(s)**

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

## **Key secondary outcome(s)**

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

## **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

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

16 years

**Sex**

Female

**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**

United Kingdom

England

Scotland

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 Hospital**

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

**ROR**

<https://ror.org/01nrxf90>

**Organisation**

NHS Lothian

**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

## 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?
<a href="#">Protocol article</a>		22/06/2023	23/06/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes