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# An international cohort study of wound closure and surgical site infection prevention strategies in abdominal surgery

**Submission date**
14/05/2025

**Recruitment status**
No longer recruiting

**Registration date**
20/05/2025

**Overall study status**
Completed

**Last Edited**
19/05/2025

**Condition category**
Surgery

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

## Plain English summary of protocol

Background and study aims
WOLVERINE stands for Wound Closure and Surgical Site Infection Prevention Strategies in Abdominal Surgery. The overall aim is to assess the different practices of wound closure techniques and surgical site prevention strategies around the world. The study will also look at the effect of wound closure and surgical site infection prevention practices on the rate of abdominal wound failure from 30 days to 1 year after surgery. The data collected will be used to help design a future interventional trial on wound closure and surgical site infection prevention. WOLVERINE was developed by the European Society of Coloproctology (ESCP).

Who can participate?
Patients aged 18 or over, undergoing abdominal surgery.

What does the study involve?
Participants agreeing to take part in the study will be asked to complete questionnaires about how they are feeling after their surgery. These questionnaires will be collected at 30 days after surgery, at 60 days, 90 days, 6 months and at 1 year. Participation will be for 12 months.

What are the possible benefits and risks of participating?
No benefits given at registration.

The research team do not expect there to be any disadvantages or risks to taking part in the WOLVERINE cohort study. However, they know that taking part takes time and completion of the questionnaires may sometimes be inconvenient.

Where is the study run from?
The cohort study is being coordinated by the ESCP team based at the University of Birmingham, UK, and the University of Birmingham is the Sponsor. A company, Ethicon, is supporting ESCP in developing educational material to help surgeons prevent surgical wound problems.

When is the study starting and how long is it expected to run for?
January 2024 to October 2026

Who is funding the study?
ESCP

Who is the main contact?
wolverine@contacts.bham.ac.uk

# Contact information

### Type(s)
Scientific, Principal investigator

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# Additional identifiers

### Integrated Research Application System (IRAS)
334321

### Protocol serial number

RG_24-006

# Study information

### Scientific Title
An international cohort study of Wound Closure and Surgical Site Infection Prevention Strategies in Abdominal Surgery

### Acronym
WOLVERINE

### Study objectives
WOLVERINE is an observational study. This cohort study will be the first large-scale international study to investigate the impact of wound closure and early wound complications on long-term outcomes.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 28/05/2024, Proportionate Review Sub-committee of the West Midlands - South Birmingham Research Ethics Committee (2 Redman Place, London, E20 1QJ, United Kingdom; -; southbirmingham.rec@hra.nhs.uk), ref: 24/WM.0115

### Primary study design
Observational

### Study design
International prospective cohort study collecting short-term clinical outcomes up to 30 days and long-term patient-reported outcomes up to 1 year

### Study type(s)
Quality of life

### Health condition(s) or problem(s) studied
Adult patients (age 18 years and above) undergoing general or colorectal surgical procedures using any type of abdominal incision measuring at least 5 cm (including extraction sites)

### Interventions
Patients will receive quality of life questionnaires at 30-days, 60-days, 90-days, 6-months and 1-year after the date of surgery.

### Intervention Type
Other

### Primary outcome(s)
1. Patient, disease, and operation-related factors are measured using patient medical notes at baseline (time of surgery)
2. Wound closure techniques are measured using patient medical notes at baseline (time of surgery)

3. Surgical site infection (SSI) prevention measures are measured using patient medical notes at baseline (time of surgery)
4. Wound healing is measured using the Bluebelle Wound Healing Questionnaire at 30, 60, and 90 days, and 6 and 12 months post-operation
5. Post-operative recovery and return to normal activities are measured using the Patient-Reported Wound Recovery PROM at 30, 60, and 90 days, and 6 and 12 months post-operation
6. Hospital re-admissions are measured using patient medical records at 30, 60, and 90 days, and 6 and 12 months post-operation
7. Re-operations are measured using patient medical records at 30, 60, and 90 days, and 6 and 12 months post-operation
8. Incisional hernia occurrence is measured using the ESCP Incisional Hernia PROM at 12 months post-operation
9. Patient quality of life is measured using the EQ-5D at 30, 60, and 90 days, and 6 and 12 months post-operation
10. Patient quality of life related to wound healing is measured using the Bluebelle Wound Healing Questionnaire at 30, 60, and 90 days, and 6 and 12 months post-operation
11. Patient quality of life related to wound recovery is measured using the Patient-Reported Wound Recovery PROM at 30, 60, and 90 days, and 6 and 12 months post-operation
12. Patient quality of life related to hernia symptoms is measured using the HerQles Questionnaire at 6 and 12 months post-operation
13. Patient-reported incisional hernia occurrence is measured using the ESCP Incisional Hernia PROM at 12 months post-operation
14. Comparison of quality of life for patients with and without wound healing issues and/or incisional hernia is measured using EQ-5D, Bluebelle Wound Healing Questionnaire, Patient-Reported Wound Recovery PROM, HerQles Questionnaire, and ESCP Incisional Hernia PROM at 30, 60, and 90 days, and 6 and 12 months post-operation

### Key secondary outcome(s)
Clinician-derived surgical outcomes data for up to 30 days post-operation

### Completion date
31/10/2026

## Eligibility

### Key inclusion criteria
1. Adult patients (age 18 years and above) undergoing general or colorectal surgical procedures
2. Elective (planned admission), expedited (within two weeks), or emergency (unplanned admission) surgery
3. General and colorectal procedures using any type of abdominal incision measuring at least 5 cm (including extraction sites)
4. Able to give written informed consent

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
99 Years

### Sex
All

### Key exclusion criteria
1. Patients undergoing incisional, ventral, umbilical, and inguinal/femoral hernia repair
2. Simultaneous hyperthermic intraperitoneal chemotherapy (HIPEC) and/or cytoreductive surgery
3. Stoma reversal without additional laparotomy incision
4. Anyone who does not have an email address or who does not have access to the internet or a smart device

### Date of first enrolment
30/05/2025

### Date of final enrolment
31/10/2025

## Locations

### Countries of recruitment
United Kingdom

England

Belgium

Denmark

Germany

Greece

India

Ireland

Italy

Netherlands

Spain

Sri Lanka

**Study participating centre**
**Wirral University Teaching Hospital NHS Foundation Trust**
Arrowe Park Hospital
Arrowe Park Road
Upton
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United Kingdom
CH49 5PE

# Sponsor information

**Organisation**
University of Birmingham

**ROR**
https://ror.org/03angcq70

# Funder(s)

**Funder type**
Research organisation

**Funder Name**
European Society of Coloproctology

**Alternative Name(s)**
The European Society of COLOPROCTOLOGY, European Society of Coloprotology, ESCP

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Associations and societies (private and public)

**Location**
United Kingdom

# Results and Publications

**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? |
|---|---|---|---|---|---|
| Protocol file | version 1.0 | 30/01/2024 | 19/05/2025 | No | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |