ISRCTN55324472 https://doi.org/10.1186/ISRCTN55324472

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
Ongoing

Last Edited
19/05/2025

Condition category
Surgery

[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
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

Contact name
Prof Thomas Pinkney

ORCID ID
https://orcid.org/0000-0001-7320-6673

Contact details
Institute of Translational Medicine
Mindelsohn Way
Birmingham
United Kingdom
B15 2TH
-
T.pinkney@bham.ac.uk

Type(s)
Public

Contact name
Mr James Keatley

Contact details
Institute of Translational Medicine
Mindelsohn Way
Birmingham
United Kingdom
B15 2TH
07305907886
j.keatley@bham.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)

334321

ClinicalTrials.gov (NCT)
Nil known

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

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

Primary study design
Observational

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
Wirral
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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
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