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Examining antibiotics for ulcerated skin cancer surgical excision

Submission date
20/06/2025

Recruitment status
Recruiting

Registration date
08/08/2025

Overall study status
Ongoing

Last Edited
11/03/2026

Condition category
Infections and Infestations

[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
Skin cancer is the most common type of cancer. Every year in the UK, around 200,000 people have their skin cancer removed surgically. Some people develop skin cancers that break through the skin surface, causing a wound on the skin (called an ulcerated skin cancer), which are six times more likely to develop a wound infection after surgery. Doctors often prescribe antibiotics at the time of surgery to prevent wound infections, but it is unknown whether antibiotics reduce the risk of getting an infection. Using more antibiotics than are needed may lead to patients having unnecessary side effects and lead to the bacteria causing the infection becoming resistant to antibiotics, which then work less well in the future. The study looks at whether antibiotics should be prescribed to patients at the time of surgically removing their ulcerated skin cancer to reduce their risk of wound infection. Participants will be given a one-off dose of antibiotic or no antibiotic (dummy pill called placebo). The study will see how many in each group develop wound infections. This will help to decide whether antibiotics should be given to patients before skin surgery.

Who can participate?
Patients with ulcerated skin cancers from participating UK NHS hospitals.

What does the study involve?
Before surgery, participants will be randomly allocated by a computer to have a one-off dose of a common antibiotic or no antibiotics (placebo). Everyone will receive the same wound care advice that they normally get as part of their NHS treatment. Participants will be asked to contact us if they are worried about their wound, and they will receive a photo booklet to help identify potential infections. They will be contacted between days 5-10, 15-20 and 30 days after surgery to ask about their wound, signs of infection and side effects. Participants will be seen in the hospital if a wound infection is suspected, and all will receive additional treatment if required. They will also be asked how long it took to return to normal activity, and the impact on daily activities.

What are the possible benefits and risks of participating?
By taking part in this trial, regardless of which treatment is received by participants, they will be helping to determine if antibiotics given just before surgery can reduce the number of wound

infections seen in patients who have this type of surgery. Participants will be followed up more closely than they would be if they were not taking part in the trial.

The antibiotic, flucloxacillin, has been used for a long time for treating skin and wound infections and has a low risk of side effects that will cause no harm to pregnant/ breastfeeding participants or male participants' partners. However, some common side effects include feeling sick, bloating, indigestion and diarrhoea. Participants will be closely monitored as part of their usual care. If participants do experience side effects, they will be encouraged to let their local recruitment site know, or if urgent, contact their GP or emergency department. Oral flucloxacillin is currently in use in the UK NHS to reduce SSI risk following skin cancer surgery. A multi-speciality clinician survey (n=129) conducted in 2021 reported that peri-operative antibiotics were 'always'/ 'often'/ 'sometimes' prescribed for excision of ulcerated skin cancers by 49% of respondents and 'rarely/ never' by 51%, demonstrating clinical equipoise. This demonstrates that both the use and non-use of the proposed intervention in the EXCISE trial are considered the current standard of practice for skin cancer surgery in the NHS. To minimise risk, potential participants with documented poor renal function (creatinine clearance < 10ml/min) or with a previous allergic reaction to penicillin will be excluded from participation. In addition to the eligibility criteria, other risk mitigation strategies include trial oversight from the Trial Management Group (TMG), Independent Data Monitoring Committee (IDMC) and Trial Steering Committee (TSC).

Participants may also be randomised to receive a placebo. This is unlikely to cause any harm as it does not contain any of the active ingredients, although it is possible that a participant could react with the excipient.

If they are diagnosed with a wound infection, they will be asked to attend their local recruiting site for review. If they are diagnosed with a surgical site infection, they will have swabs taken of the wound for antimicrobial resistance analysis in addition to those taken for standard care. These wound swabs may cause some slight discomfort. Participants will be offered compensation for travel to their local recruiting site if required to ensure that the participant is not disadvantaged.

Completion of patient diaries, taking wound photos and answering questionnaires about their health is not anticipated to cause any pain, discomfort, distress or intrusion, although it will take up participants' time.

Additionally, a selection of participants, those who declined to participate and health care professionals will be asked to take part in a semi-structured interview about their experience of taking part in the trial. It is not likely to involve any particular risks, although participating in such a discussion may bring back memories of a difficult and distressing time.

Where is the study run from?
University Hospital of Wales, UK

When is the study starting and how long is it expected to run for?
March 2026 to December 2027

Who is funding the study?
The National Institute for Health and Care Research (NIHR), UK

Who is the main contact?
Mr Burhan Ben Karatas excise-ctr@cardiff.ac.uk

Contact information

Type(s)
Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1009425

Protocol serial number
24/APR/8825E, CPMS 60084

Study information

Scientific Title
EXamining antibiotics for ulCerated skIn cancer Surgical Excision (EXCISE): a pragmatic, double-blinded clinical and cost effectiveness randomised controlled trial.

Acronym
EXCISE

Study objectives
This study wants to know whether antibiotics should be prescribed to patients at the time of surgically removing their ulcerated skin cancer to reduce their risk of wound infection. Participants will be given a one-off dose of antibiotic or no antibiotic (dummy pill called placebo). The study will see how many in each group develop wound infections. This will help us to decide whether antibiotics should be given to patients before skin surgery.

• The study will see what the side effects are for taking a single dose of oral flucloxacillin.
• The study will measure the antibiotic resistance that occurs in infected wounds by taking a swab of wounds from patients who have an infection.
• To look at the costs and benefits of the antibiotic treatment
• To look at participants' and clinicians' views on using antibiotics to prevent wound infection.
• To look at whether participants are willing and able to send wound photos.
• To validate the Wound healing questionnaire to try and decide if a patient has a wound infection without needing to do this in person.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/08/2025, Wales REC 3 (Health and Care Research Wales, Castlebridge 4, Cardiff, CF11 9AB, UK; +44 (0)2922 941107, +44 (0)2922 940954, +44 (0)2922 940963; E. Wales. REC3@wales.nhs.uk), ref: 25/WA/0196

Study design
Pragmatic double-blind randomized controlled parallel-group trial

Primary study design
Interventional

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Antibiotic treatment for the prevention of surgical site infection in participants receiving ulcerated skin cancer excision

Interventions
To investigate the efficacy of a single pre-operative 1g dose of oral flucloxacillin in preventing SSI within 30 days in adults undergoing surgical excision of an ulcerated skin cancer under local anaesthetic with planned wound closure.

Participants will receive either Intervention: pre-operative oral flucloxacillin 1g (500mg x 2) in addition to standard clinical care, or Comparator: no antibiotic (placebo) and standard clinical care.

Outcomes will be assessed at baseline, 5-10 days, 15-20 days, 30 days and at 3 months post randomisation. Data will be collected by the research nurses either in person or via telephone, email or post, or review of patient records, and entered in electronic format on the EXCISE database. Patients will be contacted at follow-up points, and if (up until 30 days) there is concern

of a wound infection, they will be asked to return to their recruiting site for a face-to-face assessment of their wound.

Participants will be randomised between the two groups (190 participants per group) with a 1:1 allocation ratio. Randomisation will occur electronically prior to surgery. Allocations will be minimised (with a random element) by SSI risk associated with reconstruction method (primary closure, skin graft or local skin flap) and anatomical site (below knee or other anatomical site) and stratified by the recruitment site. A computerised web-based remote randomisation system will be used. The Trial Manager will also be notified that a participant has been randomised via an automated email alert mechanism to the EXCISE email inbox. This system will be maintained by the Cardiff Centre for Trials Research (CTR) and accessed by the local investigator or site staff delegated to do so, following consent and completion of baseline assessments. In the event the online randomisation system is unavailable at the site, or the site has problems accessing the online website, participants will not be disadvantaged by having their surgery delayed and will be excluded from the trial.

A qualitative study will be conducted with trial participants (n=40), Health Care professionals (n=20) and those who have declined to take part in the trial (n=8). Assessment of the fidelity of possible influences on treatment outcomes in the design and implementation of surgical randomised controlled trials, factors affecting trial compliance, wound management and reporting SSI, the acceptability of treatment received, including views on antibiotics, barriers and facilitators and the wound burden.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Flucloxacillin [Flucloxacillin]

Primary outcome(s)
The proportion of participants with surgical site infection within 30 days post-randomisation. Participants will be contacted by a research nurse at days 5-10, 15-20 and day 30 (+/- 7 Days) to ask about their wound and signs of infection. If the participant or research nurse has any concerns, they will be asked to come to the participating centre to confirm surgical site infection using CDC criteria.

Key secondary outcome(s))
Secondary outcome measures
1. The number of participants with adverse events within 30 days of surgery, defined using the Medical Dictionary for Regulatory Activities
2. Antibiotic resistance to clinically relevant antibiotics, and measured in isolates from participants' wounds at diagnosis of SSI and after 7 days if no response to treatment. This will be assessed by a central microbiology laboratory (Public Health Wales)
3. Health-related QoL measured using the EQ-5D-5L questionnaire at baseline, 30 days and 3 months
4. Time to return to normal activity/work measured using 'Time to return to normal activity /work' case report form (CRF) at 30 days and 3 months
5. Resource use (related to wound complications, including SSI) and cost of hospital visits/stays,

measured using a ‘resource use measure’ CRF at 30 days and 3 months
6. Qualitative process evaluation assessing implementation and acceptability of oral antibiotics, including facilitators and barriers, measured using qualitative interviews at 30 days
7. Feasibility of ‘Selfi-wound’ photos measured using the number of participants who were able to successfully take and transmit an image of their wound via the online system at days 5-10
8. Validation of WHQ remote use for SSI assessment measured using a Study within A Trial (SWAT) at 30 days

Tertiary outcome
Qualitative process evaluation exploring participant wound burden measured using qualitative interviews at 30 days

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Adult patients (≥16 years) with a clinically ulcerated suspected skin cancer (at any body site) listed for excision under local anaesthetic with planned wound closure by any secondary care speciality.
2. First time in the EXCISE trial.
3. Ability to provide Informed Consent (by participant or through a participant’s personal legal representative).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Clinical evidence of skin cancer infection at baseline using CDC criteria.
2. Skin tumour removal planned with curettage, Mohs micrographic surgery/ margin-controlled excision or shave excision.

3. Wound left for delayed reconstruction or secondary intention healing or closed with dermal substitute.
4. Concurrent oral antibiotic treatment (<24 hours after last dose).
5. Documented poor renal function (creatinine clearance < 10ml/min).
6. Previous allergic reaction to penicillin.

Date of first enrolment
10/03/2026

Date of final enrolment
01/04/2027

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
Wales
CF14 4XW

Study participating centre
Walsall Manor Hospital
Moat Road
Walsall
England
WS2 9PS

Study participating centre
Castle Hill Hospital
Castle Road
Cottingham
England
HU16 5JQ

Study participating centre
Churchill Hospital
Old Road
Headington
Oxford
England
OX3 7LE

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
England
TS4 3BW

Study participating centre
Royal Victoria Hospital
Department of Dermatology, Belfast HSCNI Trust
Belfast
Northern Ireland
BT12 6BA

Study participating centre
Stoke Mandeville Hospital
Mandeville Road
Aylesbury
England
HP21 8AL

Study participating centre
Morriston Hospital
Heol Maes Eglwys
Cwmrhydyceirw
Swansea
Wales
SA6 6NL

Study participating centre

Northampton General Hospital
Cliftonville
Northampton
England
NN1 5BD

Study participating centre
Brighton General Hospital
Elm Grove
Brighton
England
BN2 3EW

Study participating centre
Royal United Hospital
Combe Park
Bath
England
BA1 3NG

Study participating centre
Victoria Hospital, NHS Fife
Department of Oral and Maxillofacial Surgery, Hayfield Road
Kirkaldy
Scotland
KY2 5AH

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
England
NR4 7UY

Study participating centre
West Suffolk NHS Foundation Trust
West Suffolk Hospital
Hardwick Lane

Bury St. Edmunds
England
IP33 2QZ

Sponsor information

Organisation
Cardiff and Vale University Health Board

ROR
https://ror.org/0489f6q08

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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 data are held by the Centre for Trials Research, Cardiff, UK. Applications to share the deidentified and anonymised trial data with other investigators for use in future research will be considered, subject to review of the aims and scientific methods of the application, and any contractual obligations required by organisations involved in the study. Requests for data

sharing or collaboration should be made by completing an application form available via the CTR website at https://www.cardiff.ac.uk/centre-for-trials-research/collaborate-with-us/data-requests.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.1	20/10/2025	03/12/2025	No	No
Study website		11/11/2025	11/11/2025	No	Yes