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Risks of preventative antibiotics for surgery

Submission date	Recruitment status	[X] Prospectively registered
11/03/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
30/03/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/02/2026	Surgery	

Plain English summary of protocol

Background and study aims

The use of antibiotics to prevent surgical wound (surgical site) infection is an accepted cornerstone of modern healthcare. This type of infection occurs in or around the incision a surgeon makes and affects 1 in 20 patients after surgery. In the UK, around 7 million doses of antibiotics are used each year to prevent these infections. However, the evidence supporting this practice is relatively weak and predates the use of modern surgical and anaesthetic techniques that have reduced the risk of wound infections. At the same time, there is evidence that antibiotics may be causing harm, both to individual patients and to society. An estimated 1 in 50 surgical patients have a complication directly caused by antibiotics, including kidney damage, hearing loss and allergic reactions.

As well as these well-known antibiotic harms, there are additional but poorly recognised problems in patients who report an antibiotic allergy. Up to 1 in 7 patients are labelled as allergic to an antibiotic, but the majority are not truly allergic to the antibiotic in question and therefore receive alternative antibiotics unnecessarily. The alternative antibiotic may be less effective in preventing surgical wound infection, while at the same time increasing the risk of side effects. For society, the widespread use of antibiotics leads to the development of bacteria that are resistant to these drugs, so-called antimicrobial resistance. This is recognised as a major global threat to public health. We urgently need to understand the risks and harms associated with preventive antibiotic use, so we can ensure the best possible use of these drugs, whilst minimising harm to patients.

Who can participate?

Patients aged 18 years or over undergoing one of the following surgeries: primary hip or knee replacement, internal fixation of a closed long bone fracture (upper or lower limb), colorectal resection, trans-urethral resection of prostate or bladder tumour, caesarean section, or hysterectomy (vaginal or abdominal)

What does the study involve?

To describe the relationship between preventative antibiotic use in surgery, surgical wound infections and antibiotic side effects, the researchers will assess any effect of preventive antibiotics on the frequency of wound infections after surgery, assess whether wound infections are more common for patients with antibiotic allergy labels, and describe the frequency of side effects and harms of antibiotics.

What are the possible benefits and risks of participating?
There are no risks or benefits of taking part in this study as this is an observational study.

Where is the study run from?
Barts Health NHS Trust (UK)

When is the study starting and how long is it expected to run for?
December 2021 to September 2024

Who is funding the study?
1. British Journal of Anaesthesia/ Royal College of Anaesthetists project grant (WKR0-2020-0020) (UK)
2. NIHR Doctoral Fellowship (NIHR301454) (UK)

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Integrated Research Application System (IRAS)
282161

Central Portfolio Management System (CPMS)
51951

Protocol serial number
1.0 15/12/2021

Study information

Scientific Title
Safe Antimicrobial ProPhylaxis for surgery study

Acronym
SAPPHIRE

Study objectives
The aims of the study are to provide detailed data describing the clinical effectiveness of antimicrobial prophylaxis and define the risks of harm during the perioperative period. This will include:
1. An understanding of the treatment effect of antimicrobial prophylaxis in preventing surgical site infection (SSI)
2. Description of clinically relevant harm associated with the use of antimicrobial prophylaxis
3. Details of any association between drug allergy labels and SSI

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/02/2022, Yorkshire and the Humber- Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle Upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8083; bradfordleeds.rec@hra.nhs.uk), ref: 22/YH/0040

Study design
Multi-centre observational cohort study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Use of antimicrobials as prophylaxis in surgical patients

Interventions
Observational study of routinely collected data relating to clinical care before and after surgery. Patient information will be collected on antibiotic use during and after surgery. The data collection period is for 30 days after the surgical procedure. The exposures of interest are the use of antimicrobial drugs to prevent surgical infection and the presence of an allergy label.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

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Primary outcome(s)
Surgical site infection (bacteriuria for urological surgery) within 30 days after surgery (US Centre for Disease Control Criteria), including:
1. Superficial surgical site infection data collected from medical notes and graded according to Clavien-Dindo Grading within 30 days after surgery
2. Deep surgical site infection data collected from medical notes and graded according to Clavien-Dindo Grading within 30 days after surgery
3. Organ space surgical site infection data collected from medical notes and graded according to Clavien-Dindo Grading within 30 days after surgery
4. Urinary tract infection or bacteriuria data collected from medical notes and graded according to Clavien-Dindo Grading within 30 days after surgery

Key secondary outcome(s))
1. Number of antimicrobials to treat an infection, collected from medical notes within 30 days after surgery
2. Incidence of antimicrobial side effects within 30 days after surgery:
2.1. Acute kidney injury of any cause, collected from medical notes and graded according to Clavien-Dindo Grading within 30 days after surgery
2.2. Diarrhoeal illness of any cause, collected from medical notes and graded according to Clavien-Dindo Grading within 30 days after surgery
2.3. Hearing loss, tinnitus or vertigo of any cause, collected from medical notes and graded according to Clavien-Dindo Grading within 30 days after surgery
2.4. Suspected allergic reaction to antimicrobials, collected from medical notes within 30 days of surgery and graded according to Ring and Messmer grading, grades 1-4
3. Suspected allergic reaction to any other drug, collected from medical notes within 30 days after surgery according to Ring and Messmer grading, grades 1-4
4. Incidence of postoperative infection within 30 days after surgery, collected from medical notes and graded according to Clavien-Dindo Grading within 30 days after surgery
5. Incidence of all postoperative complications within 30 days after surgery, collected from medical notes and graded according to Clavien-Dindo Grading
6. Mortality at 30 days data collected from patients' medical notes

Completion date
30/09/2024

Eligibility

Key inclusion criteria
Patients aged 18 years or over undergoing one of the following surgeries:
1. Primary hip or knee replacement
2. Internal fixation of a closed long bone fracture (upper or lower limb)
3. Colorectal resection
4. Trans-urethral resection of prostate or bladder tumour
5. Caesarean section
6. Hysterectomy (vaginal or abdominal)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Use of antibiotics in the 2 weeks prior to surgery
2. Previous participation in the study

Date of first enrolment
31/03/2022

Date of final enrolment
01/08/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
England
E1 2ES

Study participating centre
St James University Hospital
-
Leeds

England
LS9 7TF

Sponsor information

Organisation
Barts Health NHS Trust

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Government

Funder Name
British Journal of Anaesthesia

Alternative Name(s)
British Journal of Anaesthesia Ltd, BJA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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

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?
HRA research summary			28/06/2023	No	No
Preprint results		12/02/2026	19/02/2026	No	No
Protocol file	version 9.0	29/04/2024	19/02/2026	No	No
Statistical Analysis Plan	version 1	15/01/2025	20/02/2026	No	No