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A study to determine the rate of infection of wounds from abdominal operations across Nigeria

Submission date
05/07/2024

Recruitment status
No longer recruiting

Registration date
25/07/2024

Overall study status
Completed

Last Edited
29/07/2024

Condition category
Surgery

[_] 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
Infection occurring on the wound following operations on the abdomen of patients can be associated with increased costs, prolonged stay in the hospital, and other harm to the patient. It increases healthcare costs for society, which is unbearable in poorer countries such as Nigeria. For this and many other reasons, many interventions are carried out for prevention.
In Nigeria, we do not have reliable national data about these infections, making it difficult to plan on how to reduce them. This study is being carried out by a collaborative group of surgeons spanning 54 hospitals in 32 states of Nigeria.

Who can participate?
All children and adult patients undergoing emergency or elective abdominal operations

What does the study involve?
After any abdominal operation on children and adults, surgeons will purposefully inspect the wound when discharging patients from the hospital and on day 30 after the operation. They will record cases that have infections and identify conditions associated with their infections

What are the possible benefits and risks of participating?
None

Where is the study run from?
Association of Surgeons of Nigeria

When is the study starting and how long is it expected to run for?
December 2023 to October 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Adewale Adisa, ao.adisa@oauife.edu.ng

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Surgical site infection following abdominal operations: a prospective, multicenter cohort study across Nigeria

Acronym
Nigeria SSI study

Study objectives
Surgical site infection is high following abdominal operations across Nigeria

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 21/12/2023, National Health Research Ethics Committee of Nigeria (Federal Ministry of Health, Abuja, 900211, Nigeria; +234 095238367; deskofficer@nhrec.net), ref: NHREC/01/01/2007-21/12/2023

Study design
Prospective observational multicenter study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Abdominal operations

Interventions
Eligible patients will be consented for recruitment. Their demographic data and operation details will be recorded immediately after operation. Wounds will be observed for evidence of infection on the day of discharge and on day 30 after the operation. Bacteria cultured from any infected wounds will be recorded. Follow up and observations ends on day 30.

Intervention Type
Other

Primary outcome(s)
Surgical site infection (SSI) 30 days post operation, defined according to Centre for Disease Control criteria

Key secondary outcome(s))
Measured using patient records:
1. Profile of organisms detected from wound swab
2. Patient-reported time taken to return to normal activities
3. Patient-reported time taken to return to work.
4.. Mortality at day 30 after operation and its relationship to SSIs

Completion date
31/10/2024

Eligibility

Key inclusion criteria
1. Patient able and willing to provide written informed consent (signature or a fingerprint) or assent from parent or guardian
2. All children and adult patients undergoing emergency or elective abdominal operations
3. Benign, malignant and trauma cases can all be included
4. Abdominal incision with an anticipated clean-contaminated, contaminated or dirty surgical wound
5. Anticipated abdominal incision of 3cm in children or 5cm or more in adults

6. Both open surgery and laparoscopic surgery can be included
7. All secondary, tertiary, public, and privately funded hospitals that perform abdominal surgeries will be eligible

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Lower age limit
1 months

Upper age limit
90 years

Sex
All

Total final enrolment
2400

Key exclusion criteria
1. Abdominal operations with clean surgical wound, such as simple hernia repair
2. Patients undergoing caesarean section will be excluded
3. Patients who are unable to complete follow-up at post-operative day 30
4. Patient already enrolled in another trial assessing surgical site infection

Date of first enrolment
01/05/2024

Date of final enrolment
31/08/2024

Locations

Countries of recruitment
Nigeria

Study participating centre
Obafemi Awolowo University Teaching Hospitals Complex
OAUTHC
Ile-Ife
Nigeria
220005

Study participating centre
Lagos State University Teaching Hospital
Ikeja
Lagos
Nigeria
2000

Study participating centre
Nnamdi Azikiwe university Teaching Hospital
NNAUTh
Nnnewi
Nigeria
888000

Study participating centre
University of Ilorin Teaching Hospital
Ilorin
Ilorin
Nigeria
111000

Study participating centre
Aminu Kano Teaching Hospital
AKTH
Kano
Nigeria
30245

Sponsor information

Organisation
Association of Surgeons of Nigeria

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated and or analyzed during this study will be available upon request from ao.adisa@oauife.edu.ng

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			11/07/2024	No	No