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Association of the type of antibiotics used at the time of appendix removal in children with appendicitis with wound infections after the surgery

Submission date
09/02/2023

Recruitment status
No longer recruiting

Registration date
23/02/2023

Overall study status
Completed

Last Edited
26/09/2023

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
The aim of this study is to find out whether the type of antibiotics given at the time children are undergoing removal of their appendix for uncomplicated appendicitis is better than the next most commonly used alternative in terms of children experiencing wound infections in the 4 weeks after surgery.

Who can participate?
Children up to the age of 16 years who have had their appendix removed for uncomplicated appendicitis during the time period from 01/01/2014 to 31/12/2018 and whose data were collected during routine surveillance carried out in Switzerland

What does the study involve?
The study only analyses data available through mandatory routine surveillance in Switzerland.

What are the possible benefits and risks of participating?
The study does not pose a risk nor present a benefit for children whose data are analysed.

Where is the study run from?
University of Basel Children's Hospital (Switzerland)

When is the study starting and how long is it expected to run for?
December 2018 to December 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Julia Bielicki, jbielick@sgul.ac.uk

Study website
https://www.swissnoso.ch/module/ssi-surveillance/ueber-ssi-surveillance/das-modul/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Swiss SSI Surveillance

Study information

Scientific Title
Association between perioperative prophylaxis with cefuroxime plus metronidazole or amoxicillin/clavulanic acid and surgical site infections in pediatric appendectomy: a Swiss retrospective cohort study

Study objectives
Evidence supporting the use of specific antibiotic regimes in perioperative antibiotic prophylaxis administered in children undergoing appendectomy for uncomplicated appendicitis is limited. It is hypothesised that a cephalosporin-based regimen may be more effective than a non-cephalosporin-based regimen.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 22/01/2019, the local ethics committee (Ethikkommission Zentral- und Nordwestschweiz [EKNZ], Ethikkommission Nordwest- und Zentralschweiz (EKNZ), Hebelstrasse 53, 4056 Basel, Switzerland; +41 (0)61 268 13 50; eknz@bs.ch), ref: 2018-02252

Study design
Retrospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Community, Hospital

Study type(s)
Treatment

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
Children undergoing appendectomy for uncomplicated appendicitis

Interventions
The study only analyses data available through mandatory routine surveillance in Switzerland. All children up to the age of 16 years who have had their appendix removed for uncomplicated appendicitis during the time period from 01/01/2014 to 31/12/2018 and whose data were collected during routine surveillance carried out in Switzerland are included. The interventions of interest for the comparative effectiveness analysis are the application of perioperative antibiotic prophylaxis with amoxicillin/clavulanate or cefuroxime plus metronidazole as recorded in mandatory national surgical site infection surveillance in Switzerland.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Amoxicillin/clavulanate (intravenous application), cefuroxime plus metronidazole (intravenous application)

Primary outcome measure
Surgical site infections (SSIs) up to 30 days after appendectomy as captured within the Swiss national SSI surveillance programme

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/12/2018

Completion date
31/12/2019

Eligibility

Key inclusion criteria
Patients up to 16 years of age undergoing appendectomy for uncomplicated appendicitis in the study period from 2014 to 2018 in Switzerland

Participant type(s)
Patient

Age group
Child

Upper age limit
16 Years

Sex
Both

Target number of participants
3839

Total final enrolment
3839

Key exclusion criteria
1. Older than 16 years of age
2. Appendectomy carried out for complicated appendicitis (perforated, established abscess)
3. Receipt of antibiotics for perioperative prophylaxis other than the two target regimens
4. No perioperative antibiotic prophylaxis applied
5. Patients with missing procedure-related data

Date of first enrolment
01/01/2014

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Switzerland

Study participating centre
University of Basel Children's Hospital
Spitalstrasse 33
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Sponsor information

Organisation
University of Basel Children's Hospital

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Sponsor type
Hospital/treatment centre

Website
https://www.ukbb.ch

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The researchers plan to submit the results of the study to a high-impact peer-reviewed journal

Intention to publish date
01/07/2023

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be available upon request from Dr Julia Bielicki (julia.bielicki@ukbb.ch).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/09/2023	26/09/2023	Yes	No