

An assessment of the effectiveness of weight-adjusted antibiotic administration, for reduced duration, in surgical prophylaxis of primary hip and knee arthroplasty

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Title and Additional Identifiers

Submission number

44779

Public title

An assessment of the effectiveness of weight-adjusted antibiotic administration, for reduced duration, in surgical prophylaxis of primary hip and knee arthroplasty

Scientific Title

An assessment of the effectiveness of weight-adjusted antibiotic administration, for reduced duration, in surgical prophylaxis of primary hip and knee arthroplasty

Acronym

Weight-adjusted antibiotics for primary hip and knee arthroplasty

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Nil known

Protocol/serial number

nil known

Condition category

Date Applied

19/12/2023

Date Assigned

Last Edited

19/12/2023

Overall study Status

Completed

Recruitment status

No longer recruiting

Study Information

Study hypothesis

Use of a weight-adjusted antibiotic regime of prophylaxis, for a shorter duration, would not lead to increased rates of surgical site infection (SSI) in patients undergoing primary total hip and knee arthroplasty

Ethics approval required

Ethics approval not required

Ethics approval(s)

This study was undertaken as part of a quality improvement project and did not require ethics committee approval as per the guidelines of Sunnybrook Hospital.

Study design

Prospective observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Other, Safety

Overall study start date

18/09/2018

Overall study end date

31/05/2022

Condition

Patients undergoing primary total hip and knee replacement

Interventions

A cohort of arthroplasty patients undergoing primary THA/TKA with a single pre-operative dose and two post-operative antibiotic doses (old regime, OR; September to December 2018), was compared to a group of patients undergoing primary THA/TKA after the regime had been changed to a weight-adjusted pre-operative dose and a single post-operative dose (new regime, NR; January to April 2019).

Intervention Type

Drug

Pharmaceutical study type(s)

Bioequivalence

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Cefazolin

Primary outcome measure

Deep SSI rates at 2 years following surgery

Secondary outcome measures

Superficial SSI rates at 2 years following surgery

Study website

Participant information sheet

not applicable

Eligibility

Participant inclusion criteria

Undergoing elective surgery for hip and knee replacement

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

1264

Total final enrolment

1264

Participant exclusion criteria

Patients undergoing revision arthroplasty surgery or return to theatre following primary procedures were not included in this cohort

Recruitment start date

01/10/2018

Recruitment end date

30/04/2019

Locations

Countries of recruitment

Canada

Study participating centres

Study Centre

Study Centre Name

Sunnybrook Holland Orthopaedic And Arthritic Centre

Address

Wellesley Street East

City

Toronto

Country

Canada

Zip

M4Y 1H1

Plain English Summary

This study aimed to evaluate the impact of a weight based regime administered for a shorter duration, on the incidence of wound infection in a cohort of patients undergoing elective primary total hip and knee arthroplasty

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

IPD sharing plan

The datasets generated and or analysed during the current study will be available upon request from Mr Tosan Okoro- tosanwumi@hotmail.com

Intention to publish date

02/02/2024

IPD sharing plan summary

Available on request

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Type

Hospital/treatment centre

Website

<https://sunnybrook.ca/content/?page=holland-bone-joint-program>

Privacy

Public

Funder(s)**Funding Type**

Not defined

Funder**Funder Name**

Investigator initiated and funded

Payment method

Online payment

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