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Post-operative infections following spinal implant surgery; incidence and risk factors

Submission date
02/11/2023

Recruitment status
No longer recruiting

Registration date
08/11/2023

Overall study status
Completed

Last Edited
07/11/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The number of spinal surgeries has increased significantly during the last 10 years. There are important benefits of instrumented spinal surgery such as prevention of neurological deficits, pain relief, improved physical function, quality of life and patient satisfaction. Unfortunately, these benefits are to some degree negatively balanced by re-operations needed due to post-operative infections. A postoperative wound infection is associated with increased patient suffering, illness, side effects of antimicrobial treatment, vacuum-assisted wound therapy as well as increased risk of destabilization of the spine, pain and disability. The high dose and long course of resistance-driving antibiotics often used in the treatment of implant infections contribute to the overall burden of hard-to-treat microbes. Thus, the overarching and long-term aim of this study is to generate the necessary knowledge needed to reduce the rate of infections and subsequent reoperations in patients undergoing spinal surgery with implants.

Who can participate?
Patients at the study hospital undergoing primary spinal implant surgery from the age of 10 years

What does the study involve?
This is an observational study meaning that there will be no changes in standard care. The difference from standard care involves the collection of patient-related data and the sample of bacteria from the nose, skin and surgical wound as well as blood samples. The data will be used for understanding the most important risk factors associated with a post-operative infection.

What are the possible benefits and risks of participating?
There are no risks or benefits associated with participating.

Where is the study run from?
Sahlgrenska University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
January 2022 to December 2025

Who is funding the study?
1. Västra Götalandsregionen (Sweden)
2. Patientförsäkringen LÖF (Sweden)
3. Neubergs stiftelse (Sweden)

Who is the main contact?
Dr Annette Erichsen, annette.erichsen@gu

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Perispinal implant infections; incidence, risk factors, surgical site colonization and its relation to systemic antibiotic prophylaxis

Acronym
SafeSpine

Study objectives

The overarching and long-term goal of the project is to generate the necessary knowledge needed to reduce the rate of infections and subsequent reoperations in patients undergoing spinal surgery with implants.

Aims:
1. To determine the centre-specific incidence of early and late infections at Sahlgrenska University Hospital in patients undergoing spinal implant surgery
2. To evaluate risk factors for early and late perispinal implant infections (PSII)
3. To trace common opportunistic skin and nasal bacteria and determine minimum inhibitory concentrations (MIC) of prophylactic systemic antimicrobials in causative bacteria in surgical and to evaluate the relationship between:
3.1. Plasma concentrations of prophylactic antibiotics and PSII
3.2. Prophylactic antimicrobial MICs in causative bacteria for PSII
3.3. Nasal colonization of Staphylococcus aureus (S. aureus) and PSII
3.4. Inadequate incisional area decolonization and development of (early/late) PSII
3.5. Index surgery skin/implant colonizers and pathogen concordance
4. To assess how infection prevention measures are used perioperatively

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 09/03/2023, The Swedish Ethical Review Authority (Etikprövningsmyndigheten Box 2110, Uppsala, 750 02, Sweden; +46 (0)10 475 08 00; registrator@etikprovning.se), ref: Dnr 2023-00057-01

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Prevention, Treatment, Safety

Health condition(s) or problem(s) studied
Peri-spinal implant infections

Interventions
1. Skin samples from the planned incisional area and nasal samples will be taken at the preoperative visit using an e-swab. The skin samples will be repeated just before surgery. Before wound closure e-swabs will be used to collect microorganisms in the wound and on implants.
2. During surgery venous blood will be drawn at the time of incision, after 2 hours of surgery and before wound closure
3. Patients will be contacted for follow-up at 10 days, 3 months, 6 months and 1 year after index surgery.

Intervention Type
Other

Primary outcome(s)

Perispinal infections (PSII) will be measured using a predefined definition based on the European Bone and Joint Infection Society (EBJIS) criteria for joint infection; two positive cultures of the same organisms and/or sinus tract with evidence of communication or visualization of implant, and/or subfascial wound purulence will be considered definitive infection. To capture infections follow-ups are scheduled for all patients at 10 days, 3 months, 6 months and 1 year after index surgery.

Key secondary outcome(s))
1. Risk factors for PSII will be explored by collecting patient-related data perioperatively. The variables included are:
1.1. Age, years
1.2. Sex, male/female
1.3. ASA classification score (I-IV)
1.4. Body mass index
1.5. Comorbidities
1.6. Nicotine use, yes/no
1.7. Immunosuppressing treatment
1.8. Alcohol use/how many glasses of wine/week/month
1.9. Spinal diagnosis
1.10. Surgical levels involved
1.11. Type of implants used
1.12. Intraoperative bleeding, measured in ml
1.13. Length of surgery, measured in minutes
1.14. Hospital length of stay, measured in days
1.15. Pressure wounds, measured using the Norton scale
1.16. Post-operative wound infection and other hospital-acquired infections, yes/no
1.17. Prophylactic antibiotics, dose and type and serum concentration
1.18. Serum Albumin - venous blood sample
1.19. Serum-C-reactive protein - venous blood sample
1.20. Hba1C - venous blood sample
1.21. Plasma - glucose
1.22. Bacterial growth on skin and nasale; test will be taken using e-swabs and cultured on standard media
1.23. Bacterial growth in wounds and implants; tests will be taken using e-swabs
2. Adherence to intraoperative infection preventive measures, measured using a pretested observational tool during 30 full-length procedures and including:
2.1. Body temperature; measured using thermistor catheter
2.2. Door openings; number per hour
2.3. Timing of antibiotics; minutes between the end of infusion and surgical start
2.4. Skin decolonization according to guidelines; yes/no
2.5. Aseptic instrument preparation according to guidelines; yes/no
2.6. Type of ventilation system: conventional mixed or unidirectional flow

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Patients undergoing spinal implant surgery at the study hospital
2. Primary surgery for the planned spinal surgical level

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
10 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
1. The presence of a preoperative spinal or peri-spinal infection
2. Ongoing active treatment for any type of malign cancer at the time of surgery

Date of first enrolment
01/05/2023

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Sweden

Study participating centre
Sahlgrenska University Hospital
Blå stråket 5
Gotheburg
Sweden
413 45

Sponsor information

Organisation
Sahlgrenska University Hospital

ROR
https://ror.org/04vgqjj36

Funder(s)

Funder type
Government

Funder Name
Västra Götalandsregionen

Alternative Name(s)
Region Västra Götaland, Västra Götaland Regional Council, Västra Götaland region, Västra Götalandsregiona, VGR

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Funder Name
Patientförsäkringen LÖF

Funder Name
Neubergs stiftelse

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

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?

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes