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Finding the best way to use antibiotics before spinal surgery to help prevent antibiotic resistance

Submission date	Recruitment status	[X] Prospectively registered
07/09/2026	Recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/09/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/09/2026	Infections and Infestations	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Latvian Council of Science
lzp-2024/1-0303

Study information

Scientific Title
Optimization of prophylactic antibacterial therapy in spinal surgery through mechanical PKPD modelling to reduce the emergence of antibiotic-resistant bacteria

Acronym
OPATS-PKPD

Study objectives
1. To determine the concentration of preoperatively administered antibiotics in the patient's plasma and excised intervertebral disc tissue at the time of surgery.
2. To compare the concentration of antibiotics in serum and disc tissue with the degree of disc degenerative changes (Pfirrmann classification) and the status of endplates (Modic classification).
3. To evaluate the relationship between tissue antibiotic concentration and the incidence of postoperative spondylodiscitis.
4. To describe the demographic and clinical characteristics of the study population (sex, age, body weight, height, comorbidities, smoking status) in relation to the tissue pharmacokinetics of the antibiotics.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/06/2026, Institutional Ethics Committee, Hospital of Traumatology and Orthopaedics, Riga, Latvia (Duntes iela 22, Riga, LV1005, Latvia; +37167 399 300; petijumi@tos.lv), ref: 21/2026/1

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Perioperative antibacterial prophylaxis in spine surgery

Interventions
Patients will receive standard preoperative antibacterial prophylaxis (cefazolin or vancomycin) according to Hospital of Traumatology and Orthopaedics guidelines. Blood samples (5 mL) taken before prophylaxis and at prespecified time intervals (5, 15, 30, 60, 90 and 120 minutes relative to the dose) will be centrifuged (10 min at 3500 rpm). A portion (50-100 mg) of the intervertebral disc nucleus pulposus excised during the operation will be sampled. Serum and disc tissue will be frozen at -30°C and analyzed at the Riga Department of Pharmaceutical Chemistry. Antibiotic concentrations will be quantified with ultra-high-performance liquid chromatography coupled with high-resolution mass spectrometry. Patient demographics (weight, height, sex, comorbidities, smoking) and disc and endplate degeneration (Pfirrmann, Modic classification) will be analyzed. Patients will be evaluated for postoperative spondylodiscitis during hospitalization and at 2- and 4-month follow-ups.

Intervention Type
Other

Primary outcome(s)
1. The concentration of preoperatively administered antibiotics in the patient's plasma and excised intervertebral disc tissue at the time of surgery measured using ultra-high performance liquid chromatography coupled with high-resolution mass spectrometry at 5, 15, 30, 60, 90 and 120 minutes (plasma) relative to the dose, and at the time of sampling (intervertebral disc tissue)

Key secondary outcome(s)
1. The relationship between intervertebral disc (IVD) antibiotic concentrations and the severity of disc degeneration (Pfirrmann classification) as well as endplate changes (Modic classification) measured using preoperative Magnetic Resonance imaging (MRI) quantification, at preoperative MRI and IVD concentration at disc sampling

2. The incidence of postoperative spondylodiscitis measured using data collected during hospitalization and at 2- and 4-month follow-up visits with the surgeon at the end of the study

3. The preoperative association between demographic/clinical variables (age, sex, BMI, comorbidities, smoking status) and IVD antibiotic penetration, measured using data collectd from patient case notes at the end of the study

Completion date
01/01/2028

Eligibility

Key inclusion criteria
1. Patients scheduled for cervical or lumbar discectomy and/or spinal fusion with an intervertebral disc implant
2. The patient will receive preoperative antibacterial prophylaxis
3. The patient has signed an informed consent form for participation in the study
4. Age 18 years and older

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. Glomerular filtration rate <30 mL/min/1.73 m²
2. Known allergy to beta-lactam antibiotics
3. Antibacterial therapy within the last month prior to surgery
4. Patient refusal to participate in the study

Date of first enrolment
01/10/2026

Date of final enrolment
01/12/2027

Locations

Countries of recruitment
Latvia

Sponsor information

Organisation
Riga Stradiņš University

ROR
https://ror.org/03nadks56

Funder(s)

Funder type

Funder Name
Latvijas Zinātnes Padome

Alternative Name(s)
Latvian Council of Science

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Latvia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	in Latvian version 1.3	20/04/2026	09/09/2026	No	No