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The impact of urinary infection on recovery after bone surgery

Submission date 10/07/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 10/07/2025	**Overall study status** Ongoing	
Last Edited 10/07/2025	**Condition category** Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Older adults often experience urinary tract infections (UTIs) or bacterial colonization in their urinary system, even without symptoms. This study investigates whether such infections, occurring within 30 days before bone surgery, lead to complications during hospital recovery. The goal is to better understand this connection and help medical teams make more informed decisions when preparing patients for surgery. Improving preoperative screening and treatment could lead to safer outcomes for future patients.

Who can participate?
Patients aged 65 years or older and scheduled for bone surgery, either planned (elective) or emergency

What does the study involve?
Before surgery, participants will have their urine tested using routine chemical, microscopic, and bacteriological methods. If signs of infection or colonization are found, these results will be tracked during hospitalization. No additional treatments or procedures beyond standard hospital care will be introduced.

What are the possible benefits and risks of participating?
Participation carries minimal risk, as the urine tests are routine and non-invasive. Some patients might experience mild discomfort during urine sample collection, especially if a catheter is used. However, contributing to this research could help shape better care pathways for others in the future.

Where is the study run from?
Tomas Bata Hospital (Czech Republic)

When is the study starting and how long is it expected to run for?
December 2024 to July 2026

Who is funding the study?
Tomas Bata Hospital (Czech Republic)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT06896643

Secondary identifying numbers
2024-32

Study information

Scientific Title
Incidence and impact of urinary tract colonization and infection on postoperative recovery in patients undergoing bone surgery: a prospective observational study

Acronym
URIBONE

Study objectives
1. To assess whether urinary tract infection (UTI) or colonization within 30 days prior to bone-related surgical procedures in patients aged 65 years and older is associated with an increased risk of postoperative complications during hospitalization.
2. To explore the impact of specific preoperative factors—such as untreated infection, absence

of follow-up urine testing, and clinical signs (e.g. fever or subjective symptoms)—on the development and severity of postoperative complications.
3. To determine whether patient frailty, measured by the Clinical Frailty Scale, influences the likelihood of postoperative complications in patients with urinary tract infection or colonization.
4. To investigate whether patient origin (home vs social care facility) affects the incidence and severity of postoperative complications related to urinary tract status.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/12/2024, Tomas Bata Hospital Ethics Committee (Havlíčkovo nábřeží 600, 762 75, Zlín, 76275, Czech Republic; +420 (0)604994504; etickakomise@bnzlin.cz), ref: 2024-32

Study design
Prospective longitudinal multicentre observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention, Quality of life, Screening, Treatment, Safety

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Urinary infection and colonization before bone surgery

Interventions
Participants aged 65 years and older will be enrolled prior to bone-related surgical procedures and observed throughout their hospitalization. Before surgery, urine analysis (chemical and sediment) will be performed as part of the pre-anesthetic evaluation, with bacteriological sampling indicated in case of findings. Additional data will be recorded, including symptoms, fever, infection treatment status, follow-up testing, frailty score, planned surgery type, patient origin, anesthesia type, and antibiotic use. Following surgery, the occurrence of urinary infections and predefined postoperative complications (e.g. fever, delirium, septic state, death) will be monitored, along with the patient's hospital trajectory and length of stay. The total duration of observation and follow-up will correspond to the entire inpatient period from admission to discharge.

Intervention Type
Procedure/Surgery

Primary outcome measure

Urinary tract infection, assessed via clinical symptoms (dysuria, urgency, fever, nausea, etc) at 1 week before surgery

Secondary outcome measures

1. Urinary tract infection measured using urine dipstick test for nitrate-reductase and leukocyte esterase at 1 week before surgery
2. Urinary tract infection measured using chemical examination of urine and sediment: pH ≥6 at 1 week before surgery
3. Urinary tract infection measured using urine dipstick test for proteinuria at 1 week before surgery
3. Urinary tract infection measured using urine dipstick test for leukocyturia (leukocyte esterase detection) at 1 week before surgery
4. Urinary tract infection measured using urine dipstick test for pyuria (leukocyte esterase or nitrites) and observation of urine discoloration, clouding or smell change at time 1 week before surgery
5. Urinary tract infection measured using urine dipstick test for bacteriuria (leukocyte esterase and nitrites) at 1 week before surgery
6. Urinary tract infection measured using flow cytometry for bacteriuria (40–1000 bacteria/µl) at 1 week before surgery
7. Urinary tract infection measured using urine culture for bacteriuria (≥100,000 CFU/ml) at 1 week before surgery
8. Urinary tract infection measured using sulfosalicylic acid laboratory test for proteinuria (semiquantitative scale from opalescence to flocculent precipitate) at 1 week before surgery
9. Urinary tract infection measured using [urine sediment microscopy for leukocyturia (>10 leukocytes per field of view)] at 1 week before surgery
10. Urinary tract infection measured using [urine sediment microscopy for pyuria (>10 leukocytes per field of view) and observation of urine discoloration, clouding or smell change at 1 week before surgery
11. Urinary tract colonization (women) measured using urine culture from two clean-catch specimens (≥100,000 CFU/ml of same species) at 1 week before surgery
12. Urinary tract colonization (men) measured using urine culture from one clean-catch specimen (≥100,000 CFU/ml) at 1 week before surgery
13. Urinary tract colonization (catheterized specimen) measured using urine culture from one specimen (≥100 CFU/ml) at 1 week before surgery
14. Antibiotic therapy measured using record of preoperative antibiotic use and type at 1 week before surgery
15. Postoperative fever measured using body temperature >38°C at 1 week after surgery
16. Postoperative circulatory instability measured using blood pressure: MAP <70 mmHg at 1 week after surgery
17. Postoperative infection measured using clinical presentation and laboratory findings at 1 week after surgery
18. Postoperative sepsis measured using clinical presentation and laboratory findings at 1 week after surgery
19. Postoperative delirium measured using CAM-ICU assessment at 1 week after surgery
20. Postoperative antibiotic therapy measured using record of administration and duration at 1 week after surgery

Overall study start date

08/12/2024

Completion date

25/07/2026

Eligibility

Key inclusion criteria
1. Age over 65 years, including
2. Elective or acute trauma/orthopedic bone surgery
3. Urine examination as part of pre-anesthetic examination, urine + sediment, in case of suspicion - bacteriological examination
4. Signed informed consent for research as part of pre-anesthetic examination (I or II)

Participant type(s)
Patient

Age group
Senior

Lower age limit
65 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
150

Total final enrolment
100

Key exclusion criteria
1. Negative finding in urine: chemical examination + sediment preoperatively.
2. Respondent under the influence of premedication, alcohol, or drugs.
3. Sensory impairment (blindness)
4. Delirious preoperative state
5. Severe mental disorder
6. Sopor
7. Coma
8. Septic state
9. Acute respiratory failure
10. Disagreement with participation in the study

Date of first enrolment
25/07/2025

Date of final enrolment
25/07/2026

Locations

Countries of recruitment
Czech Republic

Study participating centre
Tomas Bata Hospital
Havlíčkovo nábřeží 600
Zlín
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Sponsor information

Organisation
Tomas Bata Hospital

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Sponsor type
Hospital/treatment centre

Website
https://www.kntb.cz

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Tomas Bata Hospital

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
25/07/2026

Individual participant data (IPD) sharing plan
The dataset generated and/or analyzed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication