

The impact of urinary infection on recovery after bone surgery

Submission date 10/07/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/07/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 10/07/2025	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

NCT06896643

Protocol serial number

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

Study type(s)

Prevention, Quality of life, Screening, Treatment, Safety

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(s)

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

Key secondary outcome(s)

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/ μ l) at 1 week before surgery

7. Urinary tract infection measured using urine culture for bacteriuria (\geq 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 (\geq 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 (\geq 100,000 CFU/ml) at 1 week before surgery

13. Urinary tract colonization (catheterized specimen) measured using urine culture from one specimen (\geq 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 $>38^{\circ}\text{C}$ 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

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

Healthy volunteers allowed

No

Age group

Senior

Lower age limit

65 years

Upper age limit

100 years

Sex

All

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

Czech Republic

76275

Sponsor information

Organisation

Tomas Bata Hospital

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Tomas Bata Hospital

Results and Publications

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