

# **STUDY PROTOCOL**

## **Urinary Infection and Colonization in Bone Procedures**

Version March 2025

### **POPULATION:**

For seniors aged 65 and over undergoing surgery (bone procedures, traumatology, orthopedics) in acute or elective mode, the relationship between preoperative urinary tract infection/colonization (within 30 days before the procedure) and the occurrence of predefined postoperative complications will be monitored (during the hospitalization period of patients). Among the monitored signs before surgery will be urine collection (chemical + sediment - a common part of pre-anesthetic examination), in case of findings, collection for bacteriological examination will be indicated. Furthermore, subjective complaints (present, absent), presence of fever, whether the infection/findings in the urine were treated or not, performance of control urine examination (performed, not performed).

The Clinical Frailty Scale and any administered antibiotic treatment will be recorded. After the surgical procedure, the occurrence of urinary infection (yes, no, sample not taken) will be assessed.

Postoperative complications such as fever, circulatory instability, delirium development, infection occurrence, sepsis development, and death will be monitored. The patient's trajectory during hospitalization (which departments they will be treated in, including the length of hospitalization) will be recorded.

The primary objective will be to determine the relationship between the preoperative occurrence of urinary infection or colonization in patients within the last 30 days before the procedure and the occurrence of predefined postoperative complications.

The secondary objectives will be to determine the most common postoperative complication in patients with preoperative urinary colonization and in patients with proven urinary infection. Additionally, the relationship between the preoperative Clinical Frailty Scale score in the defined patient population and the occurrence of predefined postoperative complications will be assessed. The final secondary objective will be to determine preoperative antibiotic therapy in the preoperative period.

The cohort of trauma patients undergoing surgery was chosen to ensure the homogeneity of the studied population (seniors aged 65 and over undergoing bone surgery).

### **TYPE OF STUDY:**

- monocentric, prospective, comparative, observational

### **CHARACTERISTICS OF THE EVALUATION SUBJECT GROUP (AGE STRUCTURE, GENDER, METHOD OF RECRUITMENT, REWARD FOR PARTICIPATIONS, etc):**

- Elective trauma procedures for seniors aged 65 and over, including acute trauma procedures for seniors aged 65 and over.
- Women and men.

- Recruitment at the time of indication for the procedure or setting the date of surgery, as part of the pre-anesthetic examination.
- No reward for participation
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#### **PRIMARY OBJECTIVE:**

- The primary objective will be to determine the relationship between the preoperative occurrence of urinary infection or colonization in patients within the last 30 days before the procedure and the occurrence of predefined postoperative complication

#### **SECONDARY OBJECTIVE:**

- To determine the most common postoperative complication in patients with preoperative urinary colonization.
- To determine the most common postoperative complication in patients with proven urinary infection.
- To determine the relationship between the preoperative Clinical Frailty Scale score in the defined patient population and the occurrence of predefined postoperative complications.
- To determine preoperative antibiotic therapy in the preoperative period.

#### **ENTRY CRITERIA**

- Age over 65 years, including.
- Elective or acute trauma/orthopedic bone surgery.
- Urine examination as part of pre-anesthetic examination, urine + sediment, in case of suspicion - bacteriological examination (common part of pre-anesthetic examination).
- Signed informed consent for research as part of pre-anesthetic examination (I or II), respecting informed consent as an expression of the patient's "free will."

#### **EXCLUSION CRITERIA**

- Negative urine findings: chemical + sediment examination preoperatively
- Respondent under the influence of premedication, alcohol, or drugs
- Sensory impairment (blindness)
- Delirious preoperative state
- Severe mental disorder
- Sopor
- Coma
- Septic state
- Acute respiratory failure
- Disagreement with participation in the study

#### **MONITORED SIGNS BEFORE SURGERY**

- be urine collection (chemical + sediment - a common part of pre-anesthetic examination)

- in case of positive findings (bacteriuria, pyuria, leukocytouria), collection for bacteriological examination will be indicated.
- subjective complaints (present, absent) presence of fever,
- whether the infection/findings in the urine were treated or not
- performance of control urine examination (performed, not performed)
- antibiotic therapy (yes, no, what kind of antibiotic treatment)
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#### **MONITORED SIGNS AFTER SURGERY**

- Temperature, fever
- Circulatory instability (
- Infection development, origin
- Sepsis development, origin
- Delirium development (standard procedure), scale (CAM-ICU)
- Patient trajectory during hospitalization
- Administered antibiotic treatment and its duration
- Respondent morbidity
- Respondent mortality

#### **STATISTICAL ANALYSIS PLAN**

- Data will be evaluated in collaboration with a statistician

All patient data will be pseudo-anonymized, and patients will be assigned a number. This project does not differ from the standard procedure in practice in Tomas Bata Hospital Zlín, Czech Republic.