# ORTOPOD PILOT STUDY

## MARCH 1 2025

**ORTOPOD PILOT STUDY** is a non-randomized, non-interventional clinical study that addresses the issue of perioperative neurocognitive disorder (deterioration of cognitive functions in the preoperative and perioperative period) and its impact on the occurrence of postoperative delirium.

Respondents meeting the entry criteria will undergo elective orthopaedic surgery (total hip arthroplasty) under general or regional anaesthesia. Preoperatively, they will be examined using the ALBA and POBAV tests, which serve for rapid and indicative assessment of cognitive functions. Furthermore, the functional capacity of patients will be assessed using the Clinical Frailty Scale, and depression will be evaluated using the Geriatric Depression Scale (questionnaire).

**After the procedure, during hospitalization in the ICU/PACU, screening for postoperative delirium will be conducted using the CAM-ICU tool.**

The aim of the pilot study is to verify the methodology and obtain baseline data on the incidence of cognitive dysfunction, depression, and frailty preoperatively, as well as the incidence of postoperative delirium in this group of patients before submitting a grant to AZV ČR. The main research question will be whether preoperative cognitive decline (according to the ALBA and POBAV tests) is associated with the occurrence of postoperative delirium. The second research question will be what percentage of patients with preoperative cognitive deficit (according to the ALBA and POBAV tests) undergo elective total hip arthroplasty. Secondary outcomes will include whether there are differences in the ALBA and POBAV test results before and after surgery (cognitive decline after anesthesia and surgery), whether higher Clinical Frailty Scale scores are associated with the occurrence of postoperative delirium, and whether the results on the Geriatric Depression Scale change preoperatively and postoperatively.

Key words: **postoperative delirium, screening, senior, risk factors, cognitive assessment, CAM-ICU, Amnesia Light and Brief Assessment (ALBA), POBAV**

**The study involves a homogeneous group of patients undergoing total hip arthroplasty under general or regional anesthesia. Patients meeting the study's entry criteria, who have signed informed consent to participate in the study, will be included.**

## MAIN RESEARCH QUESTION

- The main research question of the ORTOPOD PILOT STUDY is whether preoperative cognitive decline, as assessed by the ALBA and POBAV tests, is associated with the occurrence of postoperative delirium in the Czech Republic?

## SECONDARY RESEARCH QUESTIONS:

- Are higher values of the Clinical Frailty Scale before surgery (values 4, 5, or higher) associated with the worsening of cognitive functions?

- What is the percentage of patients with cognitive impairment according to the ALBA and POBAV tests before knee and hip arthroplasty surgery in hospitals?
- Are the results different in the ALBA and POBAV tests in the period before and after the surgery?
- Are higher values on the Clinical Frailty Scale before surgery (values 4, 5, or higher) associated with a deterioration in cognitive functions?

**DATA COLLECTION TOOLS AND PROCEDURES**

**Preoperatively:**

- Cognitive test ALBA and POBAV
- Clinical Frailty Scale

**Postoperatively**

- CAM-ICU (screening at least once a day) during hospitalization in the ICU

**ICU Hospitalization:**

- 0th postoperative day (4 hours after general anesthesia), 1st postoperative day, 2nd postoperative day, screening during ICU hospitalization, final screening upon discharge from ICU = exit screening

**PACU Hospitalization:**

- 0th postoperative day (4 hours after general anesthesia), 1st postoperative day, 2nd postoperative day = exit screening

**In case of postoperative delirium development:**

- Screening 2 times a day, every 12 hours

**ENTRY CRITERIA:**

- Age over 65 years (inclusive)
- Type of procedure: elective total hip arthroplasty under general or regional anesthesia
- ASA classification I-III
- Absence of sensory impairment (blindness, deafness, deaf-muteness)
- Postoperative hospitalization in the intensive care unit, post-anesthesia care unit (PACU)

**EXCLUSION CRITERIA:**

- Glasgow Coma Scale 14 or less
- Limited legal capacity
- Known psychiatric illness with the use of psychiatric medications

- Effect of premedication, psychiatric, and analgesic-sedative drugs (at the time of cognitive function testing)
- Active oncological disease
- Chronic use of strong opioids
- Re-operation