Bispebjerg og Frederiksberg Hospital

Perioperative preventive use of antibiotics, how much is necessary?

Effect of Single versus Multiple Prophylactic Antibiotic Doses on Prosthetic Joint Infections following Primary Total Hip Arthroplasty (THA): A Cross-Over, Cluster Randomized Controlled, Non-Inferiority Trial based on National Quality Databases. Protocol for The Pro Hip Quality-OA Trial.

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BACKGROUND

A feared complication after THA is prosthetic joint infection (PJI), associated with high morbidity and mortality. Using antibiotics is one of the main modifiable factors for prevention of PJIs. There is no consensus on the dosages, and current recommendations are based on low-level evidence. No randomized controlled trial has compared one preoperative dose with additional doses of antibiotic prophylaxis.

Primary Aim: The effect of a single versus multiple prophylactic antibiotic doses administered within 24 hours on PJI.

Figure 1. Treatment Allocations

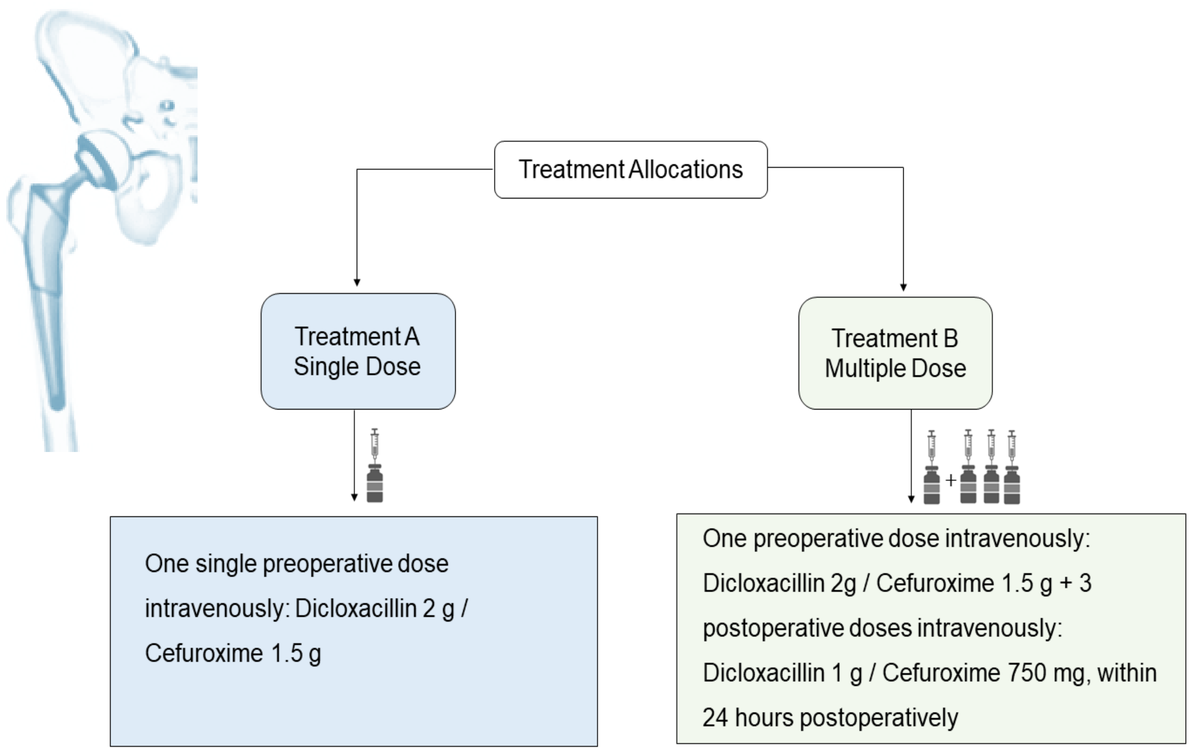
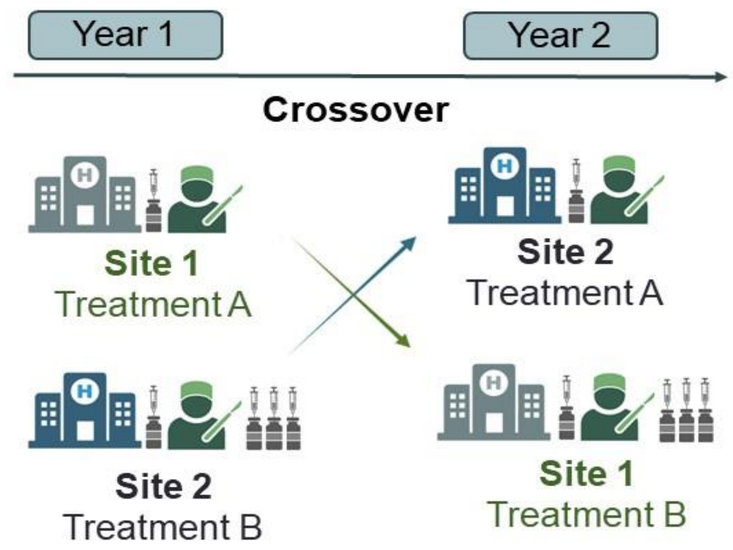


Figure 2. Trial Design and Timeline

- Year 1: sites are randomized to Treatment Arm A (single-dose) or B (multiple-dose)
- Cross-over of sites from Treatment A to B or vice versa after 1 year
- End of inclusion after 2 years



METHODS

The study is designed as a cross-over, cluster randomized, non-inferiority trial. All clinical centers use both regimes (one year of each intervention), but the order in which they use the practices is randomized.

All Danish orthopedic surgery departments will be involved. Over two years, app. 20,000 primary THAs conducted at 39 public and private hospitals, will be included.

Inclusion criteria: age ≥18 years, all indications for THA except bone tumor, metastasis, fracture and sequelae to fracture.

Primary outcome : PJI within 90 days after primary THA.
Secondary outcomes include (*i*) serious adverse events, (*ii*) potential PJI, (*iii*) length of stay, (*iv*) thromboembolic complications, (*v*) hospital-treated infections, (v*i*) community-based antibiotic use, (*vii*) redeemed prescriptions for opioids, (*viii*) acetaminophen and NSAIDS.

ANALYSIS

Analyses will be based on the Intention to Treat (ITT) population. We expect to achieve a precision in the two-sided 95% confidence interval range from -0.28% to + 0. 28%, if comparability is met.*

Outcome measures will be extracted from national databases: The Civil Registration System, The Danish Hip Arthroplasty Register, The Danish National Patient Registry, The Hospital Acquired Infections Database and The Danish National Prescription Database.

*adjusted since initial submission of abstract.

MOTIVATION

We believe, that results of this RCT will deliver necessary evidence to change clinical practice on antibiotic prophylaxis dosages in the future.

PRO HIP QUALITY-OA
ClinicalTrials.gov, ID NCT05530551

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