

# Optimizing post-tonsillectomy morbidity: a multicenter, double blinded, randomized controlled trial comparing surgical instruments

## **Abstract**

### **Introduction**

Background: Tonsillectomy, a common surgical procedure, is associated with significant morbidity, including post-tonsillectomy hemorrhage and postoperative pain. Despite previous efforts of developing hot instruments, the cold steel technique still remains the golden standard. Given the ongoing presence of postoperative complications, there is a pressing need for additional research aimed at reducing these issues.

Aim: To investigate whether tonsillectomies performed with the impedance-dependent tissue sealer device, BiZact™, reduce post-tonsillectomy hemorrhage rate and postoperative pain compared to the traditional cold steel technique.

### **Material & Methods**

Design: A multicenter, double-blinded, RCT will be implemented. Pre- and postoperative patient data are collected using the Danish Tonsil Database.

Setting: Five ENT departments in Denmark are enrolling participants.

Participants: The study includes elective and acute patients undergoing tonsillectomy for benign indications, patients above four years of age, and a weight above 16 kilograms. Exclusion criteria comprise specific medical conditions.

Exposure: Participants are randomized to undergo tonsillectomy with either cold steel or BiZact™.

### **Results**

Primary outcomes include post-tonsillectomy hemorrhage and postoperative pain. Secondary outcomes comprise perioperative variables, complications to tonsillectomy, unscheduled healthcare contacts, and patient-reported outcomes.

### **Conclusions**

Based on preliminary results showing a reduced rate of post-tonsillectomy hemorrhage with the use of BiZact™, we anticipate that BiZact™ is noninferior or better than the cold steel technique in terms of post-tonsillectomy hemorrhage and postoperative pain, potentially challenging the gold standard status of the cold steel technique. This research seeks to ensure more favorable, less painful, and less costly postoperative period after tonsillectomy.