

## **Nordic co-operation in clinical trauma research- A proximal humerus fracture RCT in Finland and in Sweden**

Antti P Launonen<sup>1</sup>, Vesa Lepola<sup>1</sup>, Karl-Åke Jansson<sup>2</sup>, Hans Berg<sup>2</sup>, Juha Paloneva<sup>3</sup>,  
Johanna Ojanperä<sup>4</sup>, Niko Strandberg<sup>5</sup>, Minna Laitinen<sup>1</sup>, Ville M Mattila<sup>1,2</sup>

1.Tampere, Finland, 2.Stockholm, Sweden, 3.Jyväskylä, Finland, 4.Kuopio, Finland, 5.Turku, Finland

Background: Proximal humerus fracture is the third most common fracture in persons over 60 years and it has been suggested that its incidence is increasing. Despite the health care resources consuming nature, the optimal treatment of proximal humerus fracture is poorly known.

Design: This study is a prospective, randomized, bi-national multi-center trial. The hypothesis of the trial is that surgical treatment of displaced proximal humerus fractures achieves better functional outcome and pain relief compared to conservative treatment in patients 60 years and older. The trial includes two strata. Stratum I compares surgical treatment with locking plates to conservative treatment for two-part fractures. Stratum II compares multi-fragmented fractures, including three- and four-part fractures. The aim of Stratum II is to compare conservative treatment, surgical treatment with locking plate, and hemiarthroplasty. The primary outcome measure will be the Disabilities of the Arm, Shoulder and Hand (DASH) score. The study is registered and the study protocol has been published.

Patient recruiting started in Tampere University Hospital in 2011. Other consortium parties are Central Finland Central Hospital (Jyväskylä), Kuopio University Hospital, Oulu University Hospital, Turku University Hospital and Karolinska University hospital. We have a study nurse in Tampere taking care of randomization and maintaining study patient records. The main outcome measure (DASH) has been validated in Finnish and in Swedish language. Orthopedic surgeons responsible for study in each center communicate with e-mail and visit each other annually. In addition to clarified written inclusion criteria in study protocol, inclusion and exclusion has been frequently discussed over each patient before the patient's acceptance to ensure comparability between inclusion and exclusion criteria in each center.

Up to date, we have included and treated 84 patients. Taken into account the public, free health care system and similar treatment policies in Finland and in Sweden, we can warmly recommend Nordic

co-operation in trauma research. We think that it offers an invaluable possibility to do high quality clinical research.

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