

MetaCARpalBOne Osteosynthesis trial (CARBO) - study protocol

Elsa Pihl^{1,2,3}, Viktor Schmidt^{1,2,3}, Michael Axenhus^{1,2,3}, Nina Brodin⁴, Sara Edsfeldt⁵, Jarkko Jokkihara⁶, Marcus Landgren⁷, Daniel Muder⁵, Fredrik Peyronsson⁵, Astrid Rosenberg⁸, Cecilia Stalberg Ostwald⁵, Sofia Svärning^{1,2,3}, Endre Soreide⁸, Mats Wadsten⁹, Cecilia Mellstrand Navarro^{1,2,3}

¹ Ortopedkliniken Danderyds sjukhus, ² Karolinska Institutet Institutionen för kliniska vetenskaper Danderyds sjukhus, ³ Danderyd Wrist and Hand Initiative, ⁴ Karolinska Institutet Institutionen för neurobiologi, vårdvetenskap och samhälle, ⁵ Uppsala Universitet, Institutionen för kirurgiska vetenskaper, ⁶ Tampere University Neurological and Sensory diseases, Oncology, Surgical sciences, ⁷ University of Copenhagen Department of Clinical Medicine, ⁸ Division of Orthopaedic Surgery, Oslo University Hospital, Oslo, Norway; Institute of Clinical Medicine, University of Oslo, Oslo, Norway., ⁹ Umeå University, Department of Surgical and Perioperative Sciences

Background

Metacarpal shaft fractures account for 30-50% of hand fractures, Current standard care of displaced diaphyseal metacarpal fractures involves operative fixation. However, retrospective studies have indicated that nonoperative treatment, involving early mobilization or buddy taping, can achieve outcomes comparable to operative treatment. There is only one published, with a small sample size, randomized controlled trial (RCT) investigating this issue. This highlights the need for a robust multicenter RCT to address these gaps in evidence.

Aim

To compare the one-year outcomes of non-operative treatment involving immediate unrestricted mobilization versus operative treatment of displaced oblique or spiral diaphyseal metacarpal fractures in adults.

Materials and Methods

This is a multicenter, pragmatic, prospective RCT involving 400 adult patients with displaced oblique and/or spiral diaphyseal metacarpal fractures of the second to fifth ray. Participants will be randomized 1:1 to receive either nonoperative treatment with unrestricted mobilization and rehabilitation) or operative treatment (with screw or plate fixation) followed by rehabilitation.

The primary outcome is grip-strength in the injured hand presented as the percentage of the grip-strength in the contralateral hand at one year. Secondary outcomes include questionnaires, complications, range of motion, patient reported outcome measures, health related quality of life, patient satisfaction, and radiographic healing.

A power calculation proposes a study size of 400 participants to detect a noninferiority margin of 10% in grip strength.

Conclusions

The purpose of the project is to optimize the treatment of metacarpal fractures by generating high-quality scientific knowledge regarding surgical and non-surgical treatment.