Post-traumatic osteoarthritis of the wrist in elderly patients with displaced intra-articular distal radius fractures. A follow-up study of the DART trial (The effectiveness of surgery versus casting for elderly patients with Displaced distal intra-Articular Radius fractures. A randomized controlled Trial).

SUMMARY

Rationale: Continuing controversy exists in the best treatment of intra-articular distal radius fractures in the elderly. The ultimate aim of treatment is to restore articular congruity to prevent complications such as secondary post-traumatic osteoarthritis. Treatment of choice depends highly on the surgeon's preference and functional demands of the elderly patient. Currently, the development of post-traumatic osteoarthritis is unclear regarding the relation to trauma as well as regarding the best treatment. Furthermore, the development of osteoarthritis in relation to the healthy contralateral side (which projects the natural course of osteoarthritis) and in relation to functional outcomes in the elderly are not known.
Objective: Assessing the post traumatic and degenerative radio-carpal osteoarthritis of open reduction and internal fixation compared with non-operative treatment for elderly patients with an intra-articular distal radius fracture.
Study design: A prospective cohort study with a four year follow up study on the DART study (The effectiveness of surgery versus casting for elderly patients with Displaced distal intra-Articular Radius fractures. A randomized controlled Trial) (NL56858.100.16, R16.013/DART).
Study population: All subjects of the DART study or subjects with an AO type C fracture from the NITEP Nordic Radius study (patients aged between 65 years and older with displaced intra-articular distal radius fractures, with an inacceptable reduction fracture characteristics within 3 weeks following trauma).
Intervention (if applicable): Not applicable. Patients have been randomized between open reduction and internal fixation (intervention group) and plaster immobilization (control group) during the DART study or NITEP Nordic Radius study.
Main study parameters/endpoints: The degree of radio-carpal osteoarthritis will be evaluated 2 and 5 years after the intra-articular distal radius fracture on X-ray and on CT scan. An assessment will be made if there is a correlation between the primary outcome and secondary outcomes, such as patient reported outcome measures (PROMs) including the Patient-Rated Wrist Evaluation score (PRWE), Disability of the Arm, Shoulder and Hand (DASH), Michigan Hand Outcome Questionnaire (MHOQ), Quality of life (EQ-5D-3L and 15D) and Pain Catastrophizing Scale (PCS). Further secondary outcomes are the frailty

score, range of motion (ROM), grip strength, complications and additional costs as a result of osteoarthritis.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

All study patients of the DART study will be approached and asked to participate in the DART II study. As part of the DART II, patients will have two follow-up moments; at 24 months and 60 months. Patients will be asked to fill out the questionnaires, both wrists will be examined and x-rays of both wrists will be made. Furthermore, at 60 months follow up, a CT scan will be made of both wrists. Patients are also asked to fill out a cost questionnaire combined with the EQ-5D-3L every six months.

In total study participants will spend 210 minutes to this study. This includes informed consent and the questionnaires.

Concerning the DART II study, exposure to radiation due to the extra radiographs and CT scan of the wrists is relatively low. In total it will result in approximately 0,044 mSv of radiation. Possible complications will be treated according to standard protocol.