Reviewer’s report

Title: Comparison of volar-flexion, ulnar-deviation and functional position cast immobilization in the non-operative treatment of distal radius fracture in elderly patients: a pragmatic randomized controlled trial study protocol

Version: 0 Date: 16 Jul 2017

Reviewer: Christoph Bartl

Reviewer's report:

The authors address an important topic as a good cast technique is essential to have a good outcome following conservative treatment.

The problem is described well

The intervention is described with the two arms: immediate post reduction x ray is necessary to make sure that the randomized position is achieved! - flex and ulnar deviation vs functional position

- Also a photo after hardening of the cast is recommended for control that the aimed position was achieved

- Please describe the functional position: is it in slight dorsal extension? - how much flexion and ulnar deviation acc to the Schede/Charnley position do you aim at? .....- all investigators must be trained prior to the start of the study, and introduced with a booklet specifying the two positions! - What is the initial material: plaster cast or light cast? - or is it up to the centers?

- Criteria: inclusion and exclusion criteria: what about exclusion of bilateral wrist fractures?, accompanying fractures of the elbow shoulder ipsilateral and the lower extremity? - otherwise people rate themselves too worse in the qol scores!

- Scores: prwe and dash is a good choice, - is the 15D score comparable to other studies? - are there a lot? - what about sf 12 with a pcs and mcs score?, and the EQ-5D score - qol scores should also be assessed retrospectively some days after intervention to assess the preop condition 4 weeks pre intervention, - same withe the pcs score - should be assessed after pain control after some days to minimize bias and to negative self scoring of this population!

a baseline eq 5d and pcs score is recommended to proof if patients recover from the injury - here also a paper addressing this question plate vs cast- an rct from 2014 should be included, and also
two other papers and reviews comparing surgical methods with casting techniques, that also looked at complications

- With the 3 month tpt also early recovery can be measured! - good point

- Randomization is described good

- Intervention: reduction control with x ray is necessary, additional photo is recommended als for internal control what is the range for the cast positions ? - what do you accept , concerning a deviation range

- Follow up : a 1-2 week x ray is needed to detect loss of reduction and indication for surgery

- The authors need an SAE and AE documentation - serious adverse events have to be named : cts, neurologic, ulcera, .... should be graded , and the outcome of AE and SAE should be assessed - what are the dangerous complications

- CRPS 1 must be added as the main complication - will there be differences ( cast position, number of reductions ???)

- Statistics: the new mcrd of walenkamp is important as it can be 11-14 points for the prwe and dash - 100 p scores

- Please describe exactly how much patients you need in each group - also name the person responsible for the statistics in a rct like that - add to the flow chart that after one year 40 persons in each group have to complete the 1 year FU to have enough power - 40 and 40 plus 30% drop out is not 114 or ??

- What is the primary outcome : prwe in the ITT setting - what about the conversion group to surgery - does it count as ITT- will it be the same in both groups ? - what if not ?

Also an "as-treated group " should be added - only cast group 1, , only cast group 2, and those with conversions to surgery - is additional statistics necessary ?

- 12 month follow up assessing the scores should be done in the clinic , also with a doctor

- Recommended additional explanatory variables: recovery 1 y after intervention in a QoL score - eg eq5d, 15D, Sf 12 - baseline score is mandatory in my view- .. and easy to manage, complications , Fracture type : - use common classifications like the AO -cl- to be comparable patients must be comparable in the 2 groups : assess,, fracture type, age, sex, eg ASA classification for acc. illnesses, .....osteoporosis , Bisphosphonate use , ....

- Add photos of the cast positions in this publication to show what you mean with the 2 positions
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

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