Volume CT of the wrist and carpus after Trauma

Published: 03-04-2013
Last updated: 24-04-2024

To perform a pilot study to quantify difference in treatment plans based on CR, as compared to treatment planning based on CT in all patients with clinical suspicion of fractures of the wrist and carpus. Information from this pilot study will be…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Observational invasive

Summary

ID

NL-OMON38460

Source
ToetsingOnline

Brief title
VuisT study

Condition

- Bone and joint injuries
- Fractures

Synonym
carpal fractures, Wrist fractures

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Computed tomography, Distal radius, Scaphoid, Wounds and Injuries

Outcome measures

Primary outcome

The main study parameter is the proportion of patients with prospectively

documented treatment changes after CT.

Secondary outcome

One secondary endpoint is the proportion of patients with difference in

fracture pattern detection before and after CT.

Second secondary endpoint is mean patient outcome according to the patient

rated wrist/hand evaluation (PRWHE) score.

Study description

Background summary

Fractures of the wrist and carpus are very common, especially fractures of the distal radius scaphoid. If treated inadequately, these fractures cause longterm pain and disability. Conventional radiography of the wrist and carpus (CR) is the standard imaging test in diagnosing fractures. However, CR underestimates the presence of fractures and severity of fracture patterns. Computed tomography of the hand and wrist (CT) improves fracture detection and treatment planning in this type of injury. CT is not accepted as a standard imaging modality in all patients with suspicion on fractures, as this is a time-consuming and expensive investigation with relatively high ionizing radiation dose as compared to CR.
We implemented a fast set-up and low-radiation dose volume CT protocol in our clinic. We hypothesize that standard use of this CT in all patients with suspicion of fractures of the wrist and carpus increases fracture detection and changes treatment plans in a substantial number of patients, ultimately improving longterm patient outcome.

Study objective

To perform a pilot study to quantify difference in treatment plans based on CR, as compared to treatment planning based on CT in all patients with clinical suspicion of fractures of the wrist and carpus. Information from this pilot study will be used to ultimately perform a randomised controlled trial to to investigate the effect of standard CT on patient outcome.

Study design

Prospective, observational pilot study

Study burden and risks

All patients will undergo CT scanning of the hand and carpus, although for some patients this is not according to clinical guidelines. This CT is associated with a radiation dose of approximately 0.05 mSv, which encompasses a trivial risk as compared to the natural background radiation in the Netherlands (2 mSv). All patients have to complete an online questionnaire (PRWHE score) with 17 questions during their vistit at the department of radiology and after 6 weeks, 6 months, and 1 year.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients (18 years and older) who are referred to our hospital for conventional radiography of the wrist and carpus and a recent trauma mechanism (within 3 days before presentation) and clinical suspicion of fractures of the wrist and carpus.

Exclusion criteria

-Patients who were not evaluated by a clinician before imaging was performed
-Open fractures
-No informed consent or no prospective data collection could be obtained
-Patients who cannot be positioned in upright position, immobilized on a spineboard or transferred to the intensive care unit and cannot undergo upright CT
-(Suspected) pregnancy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-06-2013
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	03-04-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL43482.091.13

Study results

Date completed:	30-04-2015
Actual enrolment:	100