Diagnostics and fracture healing of scaphoid fractures with High-Resolution Peripheral Quantitative Computed Tomography (HR-pQCT)

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

Summary

ID

NL-OMON46830

Source
ToetsingOnline

Brief title
Diagnostics and fracture healing of scaphoid fractures with HR-pQCT

Condition

- Bone and joint injuries
- Fractures

Synonym
carpal navicular fracture, Scaphoid fracture

Research involving
Human

Sponsors and support

Primary sponsor: Viecuri Medisch Centrum voor Noord-Limburg
Source(s) of monetary or material Support: Fonds Wetenschap en Innovatie VieCuri

Intervention

Keyword: - Diagnostics, - Fracture healing, - HR-pQCT, - Scaphoid fracture

Outcome measures

Primary outcome

Phase I * Diagnostic phase

The main outcome parameter is the proportion of patients with a diagnosed

scaphoid fracture based on either CT or HR-pQCT or CT and HR-pQCT.

Phase II * Follow-up phase

The main outcome parameters for Phase II are the changes in cortical and

trabecular bone parameters assessed by HR-pQCT and the changes in estimated

bone strength and stiffness as calculated in the µFEA.

Secondary outcome

Secondary outcome parameters for Phase II are the standard clinical and

functional outcomes that are obtained using the PRWHE-DLV questionnaire, the

pain score using VAS, the range of motion assessment and hand grip strength.

Study description

Background summary

The scaphoid bone is the most common fractured carpal bone. Scaphoid fractures represent 2-6% of all fractures and occur mainly in young, active patients aged 15 to 40. The scaphoid bone has an essential role in functionality of the

wrist, acting as a pivot. Correct treatment of a scaphoid fracture depends on accurate and timely diagnosis, and inadequate treatment can result in avascular necrosis (up to 40%), nonunion (5-21%) and early osteoarthritis (up to 32%) that may seriously impair wrist function. In addition, impaired consolidation of scaphoid fractures results in longer immobilization leading to significant functional and psychosocial impairment thus having considerable socio-economic consequences and negative impact on the quality of life.
Current diagnostic pathways can take up to two weeks to diagnose (or exclude) a scaphoid fracture, leading to overtreatment in patients with a suspected scaphoid fracture since only 15 to 30% of suspected scaphoid fractures in the Netherlands annually is found to be an actual fracture.
Thus, there is significant room for improvement in the diagnostic pathway of scaphoid fractures.

Study objective

Phase I - Diagnostic phase
The primary objective is to compare the clinical diagnostic performance of HR-pQCT with conventional CT imaging for diagnosis of scaphoid fractures.
We hypothize that the use of the HR-pQCT in patients with a suspected scaphoid fracture increases fracture detection, followed by appropriate treatment in an earlier stage.

Phase II * Follow-up
The primary objective is to quantify the healing of diagnosed (either CT, HR-pQCT or both) and conservatively treated scaphoid fracture using HR-pQCT within 6 months after fracture.
The secondary objective of phase II is to investigate whether early changes in bone strength and structure parameters can predict the 6-month functional outcome.

Study design

In this explorative stepwise study, patients suspected of having a scaphoid fracture will be scanned with HR-pQCT at the same time as the conventional CT is performed in the routine workup of these patients (Phase I). Patients with a radiographically confirmed and conservatively treated scaphoid fracture based on CT or HR-pQCT will be asked to enroll in Phase II, with follow-up HR-pQCT scans and questionnaires up to 6 months post-fracture.

Study burden and risks

Patients do not have any direct benefits from participation in this study . The risks are limited.
Phase I: In addition to the X-ray and CT scan as part of the regular care, a HR-pQCT scan will be performed. For this study, all patients with a suspected

scaphoid fracture will undergo CT scanning. For a minority of patients, this is not according to the current clinical guideline. The radiation dose from the CT scan is 11.5 *Sv, which is 1.7% of the individual annually background radiation in the Netherlands. The radiation dose from this single HR-pQCT scan is 15 *Sv (3 stacks x 5 *Sv per stack), which is 2.2% of the individual annually background radiation in the Netherlands. The additional time to perform the HR-pQCT scan and fill-out 2 questionnaires is 45 minutes. All patients have to complete two questionnaires (PRWHE-DLV and VAS) .
Phase II: In addition to the regular X-rays as part of the follow-up of a diagnosed scaphoid fracture, four additional HR-pQCT scans (at three, six, twelve and 26 weeks after fracture) will be performed resulting in a radiation dose of 60 *Sv. The total radiation dose of this phase is 7.4% of the individual annually background radiation in the Netherlands. All patients have to complete two questionnairs (PRWHE-DLV and VAS) during the four additional visits. In addition, hand grip strength is measured three times (at six, twelve and 26 weeks after fracture) The total study visit time for phase II per subject will be 240 minutes, divided over 4 visits in a 6-month period. The regular care visits will be combined with the study visits to limit the impact of the study related activities on participants.

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

Phase 1
1. Adults (18 years or older) who visit the emergency department of the VieCuri Medical Center Venlo with a clinically suspected scaphoid fracture due to a trauma (<1 week after trauma).
2. Patients who understand the conditions of the study and are willing and able to comply with the scheduled radiographic evaluations and the prescribed treatment and rehabilitation.
3. Patients who signed the Ethics Committee approved specific informed consent form prior to inclusion.;Phase 2
1. Patients who completed Phase I of the study and have a radiographically confirmed scaphoid fracture on CT or HR-pQCT.
2. Patients who signed the Ethics Committee approved specific informed consent form prior to inclusion.
3. Conservatively treated scaphoid fractures

Exclusion criteria

Phase 1
1. Patients, who as judged by the principal investigator, are mentally compromised or are unlikely to be compliant with the follow-up evaluations schedule.
2. Scaphoid fracture at the ipsilateral side in de medical history
3. Pregnancy.;Phase 2
1. Patients, who as judged by the principal investigator, are mentally compromised or are unlikely to be compliant with the follow-up evaluations schedule.
2. Pregnancy

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-12-2017
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	02-11-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL62476.068.17

Study results

Date completed:	26-03-2019
Actual enrolment:	91