Posttraumatic osteoarthritis following distal radius fractures in young patients and the correlation with subjective and objective outcome measures

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To determine the incidence of posttraumatic osteoarthritis following distal radius fractures in a cohort of young non-osteoporotic patients and correlation with objective and subjective outcome measures.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Observational invasive

Summary

ID

NL-OMON39658

Source
ToetsingOnline

Brief title
Osteoarthritis following distal radius fractures in young patients

Condition

- Fractures
- Bone and joint therapeutic procedures

Synonym
distal radius fracture, wrist fracture

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Fonds de Gavere

Intervention

Keyword: Fracture, Osteoarthritis, Radius, Subjective

Outcome measures

Primary outcome

The incidence of posttraumatic osteoarthritis.

Secondary outcome

Subjective outcome measures objectivied with the use of validated

questionnaires (PRWE, DASH, SF-36 and MHQ). Objective outcomes measured with

functional tests such as range of motion and gripstrength. Radiological

findings measured with X-rays.

Study description

Background summary

The development of posttraumatic osteoarthritis (PA) following distal radius fractures (DRFs) has been commonly described. Direct and indirect joint impact loading, soft tissue injuries, joint dislocation and intra-articular fractures, increase the risk of progressive joint degeneration that causes PA. It is thought posttraumatic osteoarthritis develops less in younger patients. However, it might be more invalidating for a young non-osteoporotic patient to develop posttraumatic osteoarthritis and loss of function following a distal radius fracture than for an older patient. The extend of the loss of function can be objectivied using functional measures, such as range of motion and grip strength. Subjective measures to objectivy loss of function as experienced by the patient can be performed using validated questionnaires. In this study, the incidence of posttraumatic osteoarthritis following a distal radius fracture is in young patients is determined. Also, the question arises what the correlation between the existence of post traumatic osteoarthritis and the objective and subjective outcome measures is following a distal radius fracture in young

patients.

Study objective

To determine the incidence of posttraumatic osteoarthritis following distal radius fractures in a cohort of young non-osteoporotic patients and correlation with objective and subjective outcome measures.

Study design

Descriptive cohort study

Study burden and risks

According to the international commission on radiological protection (ICRP) the estimated risk for the radiological procedure (4 x-rays per subject) is categorized asIIa, very low level of risk of radiogenic cancer, >0.2 and <2 mSv. In comparison to the * Rijks Instituut Voor Milieuhygiëne (RIVM)* , the annual radiation dose in the Netherlands is 1.7 mSv. The number of visits is once for the functional physical tests combined with the radiological procedure. The physical discomfort during the functional tests and the radiological investigation is minimal. The subject will be asked to sit still for the radiological investigations for 4 times less than 1 minute.

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

All patients treated in the period 2005 untill 2011 in the Medical Center Leeuwarden with a distal radius fracture of which the x-ray after the trauma and after 6 weeks is present in the archives of the Radiology Department. Men aged between the age 18-50 years and women between the age of 18-40 years at the time of presentation.

Exclusion criteria

Fractures treated more than 7 days following initial trauma, open fractures and preexistent osteoartritis.

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):	01-09-2013
Enrollment:	80

Type:	Actual

Ethics review

Approved WMO Date:	23-07-2013
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22608
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	Aangemeld bij NTR
CCMO	NL41587.099.13
OMON	NL-OMON22608