Evaluation of indicators for distal radioulnar joint instability after a distal radius fracture in adults

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Primary objective: To estimate the incidence of clinical and radiological DRUJ instability after a conservatively treated distal radius fracture using clinical tests and CT-scan, and to assess the value of CT for diagnosing DRUJ instability using...

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

Summary

ID

NL-OMON37051

Source
ToetsingOnline

Brief title
DRUJ instabilty after DRF

Condition

- Fractures

Synonym
fore-arm instability, wrist fracture

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Bontiusstichting LUMC (contactpersoon: dhr. drs. P.A. van Luijt)

Intervention

Keyword: distal radius fracture, DRUJ, instability

Outcome measures

Primary outcome

DRUJ instability confirmed by physical examination (stress test or clunck test positive) and CT-scan.

Static clinical DRUJ instability will be diagnosed with the stress test. The test is positive if there is more anterolateral movement of the ulna, relative to the stabilized radius than compared to uninjured wrist. Dynamic clinical DRUJ instability will be diagnosed by the clunck test. During passive rotation of the wrist the ulna is compressed to the radius. This test is positive if a clunck is palpable for the subject.

DRUJ instability will be evaluated on the CT-scan of both wrist in maximal pro- and supination as described by the subluxation ratio [46]. Two lines perpendicular to a line connecting the volar and dorsal margins of the sigmoid notch are drawn from the volar and dorsal margins of the sigmoid notch. The ratio of the length of CD to that of AB is calculated. (Fig. 1). Normal values are 0.2, 0.01 and -0,13 in maximal pronation, neutral and maximal supination respectively.

Secondary outcome

o Wrist function

Physical examination will include determination of restricted or blocked pronosupination, ulnar and radial deviation, dorsal and palmar flexion using a goniometer, and grip and pinch strength using a JAMAR® Hydraulic Hand

Dynamometer and JAMAR® Hydraulic Pinch Gauge. For each patient maximal range of motion in any direction will be tested three times and measured by a goniometer. Both maximal grip and pinch strength, with the elbow in 90dgrs of flexion and shoulder in neutral position will be measured three times. The average of the three measurements will determine function. Loss of function is defined as 10% or more decrease in arc of motion (pro- and supination, ulnar-radial deviation and palmar-dorsal flexion) compared to the uninjured side.

o Malunion

Malunion is defined as the difference in radial length, radial inclination and volar tilt as confirmed on the CT, comparing the injured with the uninjured wrist. More than 10% difference is considered malunion.

o Pain

Pain is indicated on a 100-point visual analogue score. Patients will be asked to indicate their pain four times for each wrist; first time without loadbearing, the second time imagining bearing a 10kg weight. Both in rest and movement.

o Subjective health assessment

Subjective assessments of quality of life and wrist function will be obtained using the Mayo modified wrist score [5], Gartland and Werley score [15], Disabilities of the Arm, Shoulder and Hand (DASH) [23] and Short Form-36

(SF-36) [25]. Patients can fill them out at home or during their visit.

o Associated unknown traumatic changes

Associated unknown traumatic changes (additional ligamenteous or osseous changes) on CT-scan are defined as traumatic changes not mentioned on the existing investigations, nor intentionally treated during follow-up.

o Complications

Complications are defined as adverse medical responses after the treatment of the distal radius fracture during follow-up.

o Radiocarpal and DRUJ arthrosis

Arthrosis is defined as loss of cartilage and will be scored on CT according to the classification of Knirk and Jupiter. [32]

The kappa measure (*) and intra-class correlation coefficient will be computed to estimate inter-observer and intra-observer agreement for CT parameters. [10, 33, 56, 61] The values will be interpreted using the guidelines proposed by Landis and Koch [33]: values of 0.01 to 0.20 indicate slight agreement; 0.21 to 0.40, fair agreement; 0.41 to 0.60, moderate agreement; 0.61 to 0.80, substantial agreement; and more than 0.81, almost perfect agreement. Zero indicates no agreement beyond that expected due to chance alone, * 1.00 means total disagreement, and + 1.00 represents perfect agreement [33, 56].

Study description

Background summary

Rationale:
In up to 1/3 of patients suffering from a distal radius fracture wrist function is decreased due to DRUJ instability after long term follow-up. DRUJ instability is caused by disruption of the stabilizing structures of the distal radioulnar joint of which the TFCC is the most important. Disruption of the attachment of the TFCC to either the ulnar styloid or ulnar fovea may cause instability. However DRUJ instability after a distal radius fracture has also been described with an intact TFCC. Another risk factor is more than 15° of dorsal angulation of the distal radius.
Clinical DRUJ instability is either static or dynamic. Static instability is confirmed by stressing the stabilizers without rotation of the forearm, whereas in testing for dynamic instability rotational forearm movements are made. Without sedation these tests are useless in the acute setting because of pain and swelling. Radiological DRUJ instability can, among others, be confirmed by radiographs or CT-scan of the wrist. Major limitation of using these modalities is that these show the static reflection of a dynamic process, which may give rise to false negative outcomes. Furthermore in literature data on the association between clinical and radiological presentation is scarce.
Therefore the aim of this study is to obtain more insight into the incidence and predictability of DRUJ instability after a conservatively treated distal radius fracture.

Study objective

Primary objective: To estimate the incidence of clinical and radiological DRUJ instability after a conservatively treated distal radius fracture using clinical tests and CT-scan, and to assess the value of CT for diagnosing DRUJ instability using clinical tests as reference standard.
Secondary objectives:
* To assess the predictive value of risk factors on trauma radiographs for clinical and CT-measured DRUJ instability after consolidation of a distal radius fracture.
* Analysis of radiological traumatic changes (missed fractures, artrhosis) in patients with clinical DRUJ instability by comparing the injured with the uninjured wrist.
* Determination of complications after conservative treatment of distal radius fractures in short- and long term follow-up.
* Determination of inter- and intra-observer agreement on diagnosing DRUJ instability using CT.

Study design

a single-center, descriptive cohort study.

Study burden and risks

All subjects are free to participate, and to exit the study at any moment.
The subjects will not benefit from participation in the study. However, the subjects who are symptomatic but did not seek medical treatment so far, may benefit from the functional measurements and additional radiologic investigations, because these may attribute to the diagnosis and may lead to an intervention to relief their symptoms.
The included patients have to visit our hospital for approximately 45 minutes to complete the investigations, including radiography, physical examination and filling out the questionnaires. The patient will receive refunds for the travelling costs and parking.
During the CT-scan, the patient will suffer from a small amount of radiation (0.03 mSv). Since the CT-scan will give particular additional information, it cannot be replaced.
A standardized questionnaire to evaluate CT-associated risk-factors will be filled out before the investigation will be started.

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

* radiographically proven distal radius fracture in the period 2008-2010, conservatively treated in the LUMC
* age > 18 years
* distal radius consolidation, as confirmed on radiographs.

Exclusion criteria

* unwilling or unable to provide informed consent to participate in this study

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2013
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	13-11-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL41495.058.12