

Diagnostic accuracy of common imaging methods to recognise internal derangement and ligamental tears of the carpus

Submission date 17/03/2009	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 08/04/2009	Overall study status Completed	☐ Protocol
Last Edited 08/04/2009	Condition category Injury, Occupational Diseases, Poisoning	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

ACCORDS_V1.2_2007

Study information

Scientific Title

Accuracy of common radiological methods to diagnose scapholunar dissociation: a prospective diagnostic efficacy study

Acronym
ACCORDS

Study objectives

To determine the diagnostic accuracy of common imaging methods (i.e., conventional and functional radiography, arthrography, computed tomography, magnetic resonance imaging [MRI] and MR-arthrography) for determining traumatic tears of the scapholunar (SL) ligament compared to the diagnostic gold standard of wrist arthroscopy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Charité University Medical Centre Ethics Committee gave approval on the 3rd September 2007 (ref: EA1/152/07)

Primary study design

Observational

Study design

Prospective diagnostic accuracy (efficacy) observational cohort study

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Traumatic scapholunar (SL) dissociation

Interventions

Experimental tests:

Routine radiological imaging procedures (i.e., plain radiographs, cineradiography, arthrography, computed tomography, magnetic resonance arthrography).

Reference standard:

Wrist arthroscopy.

Diagnostic test accuracy will be investigated. All imaging procedures will take no longer than one hour, and wrist arthroscopy no longer than two hours (depending on intra-operative findings and the need for surgical repair). The study-specific follow-up ends at hospital discharge, since all information necessary to answer the study questions will have been collected at this time.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Diagnostic accuracy (i.e., sensitivity, specificity, areas under the receiving operating characteristics [AUC/ROC]) of all established imaging methods compared to the diagnostic reference standard (i.e., wrist arthroscopy). All outcomes will be assessed by the time of hospital discharge.

Key secondary outcome(s)

Cost-effectiveness. All outcomes will be assessed by the time of hospital discharge.

Completion date

01/01/2011

Eligibility

Key inclusion criteria

1. Male and female patients aged 18 to 65 years
2. Considered to require wrist arthroscopy due to:
 - 2.1. Exposure to an injury to the wrist (i.e., hyperextension, contusion, extra-articular radial fractures) suitable to cause SL-tears
 - 2.2. Persistent pain and/or other symptoms for greater than 4 weeks

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Pregnancy
2. Renal insufficiency
3. Known allergy to contrast media
4. Relative or absolute contraindication to MRI scanning
5. Previous operations to the affected wrist
6. Rheumatoid arthritis
7. Open fractures or other conditions deemed to require immediate surgical intervention

Date of first enrolment

01/01/2009

Date of final enrolment

01/01/2011

Locations

Countries of recruitment

Germany

Study participating centre

Dept of Hand-, Micro-, and Replantation Surgery

Berlin

Germany

12683

Sponsor information

Organisation

Deutsche Arthrose-Hilfe e.V. (Germany)

ROR

<https://ror.org/05e1k0d14>

Funder(s)

Funder type

Research organisation

Funder Name

Deutsche Arthrose-Hilfe e.V. (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration