

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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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)

## Study design

Prospective diagnostic accuracy (efficacy) observational cohort study

## Primary study design

Observational

## Secondary study design

Cohort study

## Study setting(s)

Hospital

## Study type(s)

Diagnostic

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet (German only)

## 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 measure**

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.

### **Secondary outcome measures**

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

### **Overall study start date**

01/01/2009

### **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

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

**Target number of participants**

230

**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)

**Sponsor details**

Postfach 11 05 51

Frankfurt/Main

Germany

60040

service@arthrose.de

**Sponsor type**

Research organisation

**Website**

<http://www.arthrose.de/>

**ROR**

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

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Deutsche Arthrose-Hilfe e.V. (Germany)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration