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

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

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)

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Postfach 11 05 51
Frankfurt/Main
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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