Is there an association between wrist or hand complaints and radiological imaging findings?

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24562

Source
NTR

Brief title
KLAP

Health condition

hand-wrist pathology

Sponsors and support

Primary sponsor: Reinier de Graaf Hospital, department of orthopedic surgery and department of radiology/Erasmus Medical Center, department of general practice
Source(s) of monetary or material Support: own funding

Intervention

Outcome measures

Primary outcome

The main study endpoint is the incidence of wrist and/or hand pathologies on radiography in adult patients (≥ 18 year).

Traumatic and non-traumatic diagnosed abnormalities on radiography at baseline are:
 wrist or hand fracture characteristics (fracture type, location);
 wrist or hand osteoarthritis characteristics (osteoarthritis score, location);
 no abnormalities (no fracture or osteoarthritis) were diagnosed by radiography examination.

Secondary outcome

Patient reported outcomes will be measured at baseline and 6 weeks, 3 months and 12 months after baseline. Outcomes will be measured with the Patient-Rated Wrist Hand Evaluation (PRWHE-score: see F1 submission request), Australian/Canadian Hand Osteoarthritis Index (AUSCAN: see F1 submission request), Numeric Pain Rating Scale-score (NPRS: see F1 submission request), Pain Catastrophizing Scale (PCS: see F1 submission request), Hospital Anxiety and Depression Scale (HADS: see F1 submission request), Patients Perceived Recovery and Outcome (see page 17) and the modified version of the Functional Comorbidity Index (FCI: see F1 submission request)
 Severity of symptoms (pain) of wrist or hand (PRWHE, AUSCAN and NPRS) at all time points (baseline, 6 weeks, 3 months and 12 months);
 Functional impairment of wrist or hand (PRWHE and AUSCAN) at all time points (baseline, 6 weeks, 3 months and 12 months);
 PCS and HADS will be completed at all time points (baseline, 6 weeks, 3 months and 12 months) to determine psychological factors related with the outcome;
 The modified version of the FCI will be completed at baseline to determine comorbidity;
 Patients-Perceived Recovery and Outcome will be measured at 6 weeks, 3 months and 12 months to determine perception of recovery.
In addition to the questionnaires, we will score additional outcomes.
 Rare abnormalities: anatomical variants, congenital deformations, abutments syndromes, rheumatoid arthritis, hemochromatosis, gout tophi, psoriatic arthritis, bone deformities (osteomalacia, Swann neck deformity, Boutonniere deformity);
 Neoplasia, benign tumors (chondrosarcoma, osteosarcoma, enchondroma, metastatic cancer) and malignant tumors;

Study description

Background summary

Rationale: In patients with wrist or hand complaints imaging studies are an important adjunct to history taking and physical examination. Radiographs are indicated as the first imaging test in patients with wrist or hand complaints, regardless of the duration of complaints or the suspected diagnosis.
Objective: The primary objective of the study is to assess the incidence of pathologies on radiography in adult patients with wrist or hand complaints. Our secondary objective is to describe the course and management of traumatic and non-traumatic wrist and/or hand complaints. The other objectives are to assess the association between pathologies on

radiography and complaints at baseline and the course of complaints, respectively.
Study design: A non-interventional, observational and prospective cohort study.
Study population: Patients of 18 year or older referred for radiography of the wrist and/or hand at the radiology department of the Reinier de Graaf Gasthuis (RdGG) (n=438).
Main study parameters/endpoints: The main study endpoint is the incidence of wrist and hand pathologies on radiography.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will undergo a X-ray as part of usual care. There will be no interference with the care given by health care providers. For that reason there will be no extra harm than that could arise during the regular care. Patients have to complete general questions and 7 questionnaires, at 4 consecutive moments. Questionnaires that should be completed:
1. Patient-Rated Wrist Hand Evaluation (PRWHE-score);
2. The Australian/Canadian Hand Osteoarthritis Index (AUSCAN index);
3. Numeric Pain Rating Scale-score (NPRS-score);
4. Pain Catastrophizing Scale (PCS-score);
5. Hospital Anxiety and Depression Scale (HDS-score);
6. Patient-Perceived Recovery and Outcomes;
7. The modified version of the Functional Comorbidity Index (FCI).
The patients will need approximately 12 minutes to answer all questionnaires.
Consecutive moments of measurement questionnaires:
 Moment 1: When presenting at RdGG for radiography (hard copy).
 Moment 2: 6 weeks after presentation (digital).
 Moment 3: 3 months after presentation (digital).
 Moment 4: 12 months after presentation (digital).

Study objective

To assess the incidence of pathologies on radiography in adult patients (≥ 18 year) with wrist and/or hand complaints referred for radiography by their general practitioner or secondary care specialist.

Study design

 Moment 1: When presenting at RdGG for radiography (hard copy).
 Moment 2: 6 weeks after presentation (digital).
 Moment 3: 3 months after presentation (digital).
 Moment 4: 12 months after presentation (digital).

Intervention

not applicable

Contacts

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Eligibility criteria

Inclusion criteria

 A new patients who will undergo a radiography of their wrist and/or hand;
 Referral to the radiology department of the RdGG for radiography;
 Age 18 years or over;
 Signed informed consent (see E2 submission request);
 Main problem concerns wrist and/or hand complaints.

Exclusion criteria

 Not mastering the Dutch or English language;
 Patients who have undergone imaging of their wrist and/or hand over the past 12 months because of ipsilateral complaints;
 Incapable of understanding the ramifications of participation;
 Wrist or hand infection (osteomyelitis);
 Pre-existent neurological pathology in the affected limb;

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-03-2021
Enrollment:	438
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	22-03-2021
Application type:	First submission

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
NTR-new	NL9407
Other	METC LDD : Not within the scope of research within human subjects act

Study results