

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

Gepubliceerd: 22-03-2021 Laatste bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24562

Bron

NTR

Verkorte titel

KLAP

Aandoening

hand-wrist pathology

Ondersteuning

Primaire sponsor: Reinier de Graaf Hospital, department of orthopedic surgery and department of radiology/Erasmus Medical Center, department of general practice

Overige ondersteuning: own funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

- 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).

Onderzoeksproduct en/of interventie

not applicable

Contactpersonen

Publiek

Reinier Haga Orthopedisch Centrum
Onderzoek RHOC

+31(0)79 206 5595

Wetenschappelijk

Reinier Haga Orthopedisch Centrum
Onderzoek RHOC

+31(0)79 206 5595

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- ☐ 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- ☐ 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;

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	22-03-2021
Aantal proefpersonen:	438
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum: 22-03-2021

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
----------	----

NTR-new	NL9407
---------	--------

Ander register METC LDD : Not within the scope of research within human subjects act

Resultaten