The use of a mould in acquisition of hand radiographs improves the reproducibility of scoring of bone erosions and joint space narrowing in rheumatoid arthritis, compared to conventionally acquired images.

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To evaluate the reproducibility of the SvdH score (BE and JSN of one hand) of radiographs taken with a mould compared to conventionally acquired images.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON38628

Source
ToetsingOnline

Brief title
The use of a mould in acquisition accuracy of hand radiographs.

Condition

- Autoimmune disorders
- Joint disorders

Synonym
rheuma, rheumatoid arthritis

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Stichting: the center of translational and molecular medicine

Intervention

Keyword: radiography, reproducibility, rheumatoid arthritis

Outcome measures

Primary outcome

Primary outcome:

- reproducibility of the SvdH score of the hand.

Secondary outcome

Secondary outcomes:

- reproducibility of the BE score of the hand.

- reproducibility of the JSN of the hand.

Study description

Background summary

In rheumatoid arthritis (RA) radiographic joint damage of the hands is the most important structural outcome (and burden) of the disease. To evaluate the joint damage, bone erosions (BE) and joint space narrowing (JSN; cartilage loss) are combined to a score, the Sharp van der Heijde (SvdH) score. This score includes several of the finger joints and wrist joints and comprises a combined score of BE and JSN. A major problem for this analysis is the limited reproducibility of acquisition of the radiographic images . Recently a mould was designed that enables more standardised positioning of the hand and wrist joints. It appeared from pilot observations that analyses of JSN and BE significantly improve when using radiographs taken with this mould in comparison to conventional radiographs. However, it has never been quantitatively studied whether reproducibility of acquisition is better with a hand mould than without a hand

mould.

Study objective

To evaluate the reproducibility of the SvdH score (BE and JSN of one hand) of radiographs taken with a mould compared to conventionally acquired images.

Study design

observational study.
Of one hand (the most affected one based on previous knowledge) an additional radiograph will be taken by using the mould. Patients are asked for an additional radiograph of both hands without mould (standard) and the same hand with mould after 3 months (a time span where there is no relevant progression of joint damage) when they visit the Rheumatology department again in clinical practice for DMARD control.

Study burden and risks

Of one hand an additional radiograph will be taken by using the mould. Patients are asked for an additional radiograph of both hands without mould (the standard) and the same hand with mould within 3 months when they visit the Rheumatology department again in clinical practice for DMARD control. This will result in a minimal increase in X-ray exposure which is considered acceptable (report attached). There will be no direct benefit for the patients involved. Knowledge may improve acquisition of hand X-ray images in the future to improve evaluation of joint damage for patients with RA.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Diagnosis of rheumatoid arthritis
Age >18 years
Radiographic hand image acquisition in regular care needed
Revisit three months later within regular care
Capable of giving informed consent
Informed Consent signed

Exclusion criteria

Other diseases than RA
No hand radiographs in regular care needed
No revisit in regular care needed within 3 months later
Not capable of giving informed consent
No Informed Consent signed
Those with hand radiographs taken more than once a year (which is regular care)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-08-2014
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	A mould for the hand: to position the hand optimally for radiography.
Registration:	No

Ethics review

Approved WMO

Date:	25-10-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL45487.041.13