Hemodynamic response assessed by the *HandScan* in hand and wrist joints of patients with osteoarthritis compared to patients with rheumatoid arthritis

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

Summary

ID

NL-OMON44590

Source
ToetsingOnline

Brief title
HandScan hemodynamic response,OA compared to RA; a pilot

Condition

- Autoimmune disorders
- Joint disorders

Synonym
'OA', Osteoarthritis, 'RA', Rheumatoid Arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Hemics B.V.,UMC Utrecht Reumatologie & Klinische Immunologie;Hemics B.V.

Intervention

Keyword: HandScan, Hemodynamic response, Osteoarthritis, Rheumatoid Arthritis

Outcome measures

Primary outcome

* Hemodynamic response, as provided standard by the HandScan (continuous value,

0-3 per joint).

* Inflammation defined by US: Gray scale (0-3 per joint) and Power Doppler (0-3

per joint)

Secondary outcome

Difference in disease characteristics detectable by US; bone osteophytes (0-1),

tenosynovitis (0-1).

Study description

Background summary

Osteoarthritis (OA) of the hand is one of the most prevalent OA phenotypes and occurs frequently in older individuals, especially women. In the general population aged >55 years, 56% of individuals have radiographic signs of hand OA, 16% experiences pain, and 3.3% experiences disability. Pain is a major burden of hand OA. It is a variable symptom, and is associated with structural damage (osteophytosis, joint space narrowing) and inflammation.
In OA, joint inflammation is increasingly considered an important target for treatment to prevent tissue damage.

Recently, a new method has been proposed for measuring inflammation of the hand and wrist joints in rheumatoid arthritis (RA). The technology is based on quantifying the inflammation related hemodynamics around the joint in response

to temporarily obstructed venous blood flow.

For RA, taking all relevant joints together, a good agreement between the HandScan values and US measurements of inflammation is found (r=0.71). HandScan measurements were even superior compared to physical examination (r=0.53), assuming US as a more sensitive (gold) standard for joint inflammation. Importantly, in patients with subclinical disease activity (inflammation not detectable by physical examination), there was a correlation between HandScan values and MRI synovitis score (r=0.57, p=0.008). Using US as a gold standard, a cut-off of 0,26 defines inflammation in hand joints of RA patients with the HandScan with a sensitivity of 77% and a specificity of 74%.

In the present explorative study we will evaluate for the first time the characteristics of the hemodynamic response as measured by the HandScan in OA and compare these characteristics to RA with the use of US to define differences in underlying pathology.

Study objective

The aim of this exploratory study is to compare the hemodynamic response as determined by the HandScan between patients with OA and RA, and to study these hemodynamic responses in relation to disease specific underlying joint pathology (synovial tissue inflammation, bone changes, and peri-articular soft tissue inflammation) as determined by US.

Primary:
To explore whether the hemodynamic response, as measured by the HandScan, is different for OA and RA, because of differences in underlying joint pathology, as measured by US.

Secondary:
To explore whether the outcome of the HandScan measurements are associated with disease related self-reported pain and tender and swollen joints by manual clinical examination,

Study design

This study is an exploratory cross-sectional, non-therapeutic observational study.

Intervention

Per patient a HandScan measurement, an US of hands and wrists and physical examination is performed.

Study burden and risks

Risk for patients is negligible, and there is no direct benefit for the patients. However, benefit for future clinical practice is anticipated. This pilot study will investigate hemodynamic response in joints of patients with OA in comparison to RA by use of the Handscan which is a first step towards a potential novel method for quick and objective detection of joint inflammation in hand OA in addition to 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

* Diagnosed with Rheumatoid Arthritis according to ACR/EULAR 2010 criteria or with OsteoArthritis according to ACR 1990 criteria.
* Age between 18 and 90 years
* * 1 swollen hand joints

* Ability to give informed consent

Exclusion criteria

* Other diagnosis than OA or RA that can explain pain or swelling in the hand joints, such as other inflammatory rheumatic diseases (psoriatic arthritis, gout).
* Intra-articular treatment with steroid injection within 3 months of assessments of the joints
* Trauma or surgery of one of the hand joints within 6 months of assessments of the joints
* Light sensitivity, i.e. Erythropoietic protoporphyria or patients on photodynamic therapy
* Artificial joints of wrist/hand

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-05-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	14-04-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-08-2016

Application type:	Amendment
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	NL50848.041.15