Performance of the HandScan in tight control treatment of Rheumatoid Arthritis

Published: 14-01-2015
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Primary: to compare improvement on the Health Assessment Questionnaire (HAQ) between HandScan guided tight control and treat-to-target treatment and the conventional ACR/EULAR remission guided tight control and treat-to-target treatment of RA after...

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

Summary

ID

NL-OMON47182

Source
ToetsingOnline

Brief title
HandScan in rheumatoid arthritis

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: LSH Impuls subsidie (TKI toeslag) van het

Topconsortium voor Kennis en Innovatie voor de Life Sciences and Health (TKI LSH),Hemics B.V. en door LSH Impuls subsidie (TKI toeslag) van het Topconsortium voor Kennis en Innovatie voor de Life Sciences and Health (TKI LSH). ,Reumafonds en door het topsectorenbeleid via een LSH Impuls subsidie (TKI toeslag) van het Topconsortium voor Kennis en Innovatie voor de Life Sciences and Health (TKI LSH).

Intervention

Keyword: HandScan (Optical Spectral Transmission), Rheumatoid Arthritis, Tight-control treatment, Treat-to-target

Outcome measures

Primary outcome

the Health Assessment Questionnaire (HAQ)

Secondary outcome

Cost-effectiveness

Radiological damage

Time until remission

Study description

Background summary

The treatment of rheumatoid arthritis (RA) has significantly been improved over the past years due to earlier and more intensive treatment including the use of biologicals. Due to the demanding approach of tight control and treat-to-target treatment in an early stage, these principles have not yet been adequately implemented in general hospitals. Recently, the HandScan has been developed, to objectively assess disease activity in RA patients in only 1.5 minutes. Our hypothesis is that clinical efficacy of HandScan remission guided treatment is at least as good as and more cost-effective than the conventional ACR/EULAR remission guided treatment. This makes this novel imaging technology more cost-effective allowing implementation in standard rheumatology care.

Study objective

Primary: to compare improvement on the Health Assessment Questionnaire (HAQ) between HandScan guided tight control and treat-to-target treatment and the

conventional ACR/EULAR remission guided tight control and treat-to-target treatment of RA after 1 * years. Secondary: to compare cost effectiveness of both arms, based on customized cost questionnaires. Tertiary: to evaluate radiographic joint damage based on a fully automated radiographic scoring of the hand joints as well as the Sharp van der Heijde score in both study arms.

Study design

Randomized double-blind controlled trial comparing the ACR/EULAR remission criteria guided treatment with the HandScan remission guided treatment in rheumatoid arthritis.

Intervention

HandScan guided treatment strategy

Study burden and risks

All included patients visit the outpatient clinic every month to assess disease activity as needed for the tight control strategy in clinical practice. At baseline, 3 months, 6, 12, and 18 months, patients are asked to fill in the Health Assessment Questionnaire (HAQ; 1st outcome), the health survey SF36, EQ5D and the questionnaire on direct and indirect costs. Radiographs of hand and feet are taken at baseline and at 18 months according to clinical practice. Since the HandScan guided treatment is novel, treatment strategy decision may in theory deviate too much from proven standard tight control care leading to undesired over- or under treatment. This will be monitored extensively during the study and the treatment strategy will be adjusted if needed (see paragraphs 3.16 en 5.5).

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

Male or non-pregnant, non-nursing female
>= 18 years of age
Early RA patients, fulfilling 2010 ACR/EULAR criteria: Evidence of clinically apparent arthritis < 1y as assessed by a rheumatologist
Patients able and willing to give written informed consent and comply with the requirements of the study protocol

Exclusion criteria

Significant visual deformations of hands or fingers
Rheumatic autoimmune disease other than RA
Current inflammatory joint disease other than RA (e.g. gout, reactive arthritis, psoriatic arthritis, seronegative spondyloarthropathy, Lyme disease)
Known porphyria (HandScan risk analysis).
Contraindication for methotrexate or prednisolone
Glucocorticoids used for RA < 6 weeks prior to baseline (NB: inhaled glucocorticoids are allowed)
Previous treatment with any DMARD that is used in the treatment of RA
Previous treatment with any biological drug that is used in the treatment of RA
• Treatment with any investigational agent within 4 weeks (or 5 half-lives of investigational agent, whichever is longer) before screening.
Patients using photodynamic therapy medication (HandScan risk analysis).
History of alcohol, drug, or chemical abuse within the 6 months prior to screening
Neuropathies or other painful conditions that might interfere with pain evaluation
Psychological or intellectual disorders that impede to participate in the study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-04-2017
Enrollment:	112
Type:	Actual

Medical products/devices used

Generic name:	HandScan
Registration:	No

Ethics review

Approved WMO Date:	14-01-2015
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	05-08-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	24-08-2015
Application type:	Amendment

Review commission:	METC NedMec
Approved WMO Date:	15-02-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	24-05-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	02-08-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-09-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-11-2018
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29197
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL50026.041.14
OMON	NL-OMON29197