TREAT EARLY ARTHRALGIA TO REVERSE OR LIMIT IMPENDING EXACERBATION TO RHEUMATOID ARTHRITIS

Published: 01-12-2014
Last updated: 17-01-2025

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50483

Source
ToetsingOnline

Brief title
TREAT EARLIER

Condition

- Other condition
- Autoimmune disorders

Synonym
artralgia, Clinical Suspect Artralgia

Health condition

gewrichtsaandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Zon Mw

Intervention

Keyword: Clinical Suspect Atralgia, Early treatment, joint inflammation, positive MRI for subclinical

Outcome measures

Primary outcome

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Secondary outcome

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Study description

Background summary

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Study objective

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Study design

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Intervention

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Study burden and risks

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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

1. Age >= 18 years, 2. Patients without clinically detectable arthritis but with arthralgia of small hand or feet joints of recent-onset (<1 year) that according to the rheumatologist is suspect to be an early presentation of RA (this symptom complex is called Clinically Suspect Arthralgia, CSA), 3. Extremity MRI positive for subclinical inflammation., 4. Ability and willingness to give written informed consent and to comply with the requirements of the study protocol

Exclusion criteria

1. Symptoms or signs making diagnoses other than RA more likely. These are

amongst others >6 tender points or Heberden or Bouchard nodules (the presence of such characteristics preclude CSA) , 2. Presence of, or history of, clinically apparent arthritis (this precludes CSA), 3. Previous or current treatment with DMARDs or corticosteroids (this precludes CSA), 4. Contra indications for MRI: certain metal implants, pacemakers, GFR<30 ml/min., 5. Pregnancy or the wish to become pregnant, breast feeding, 6. Bone marrow hypoplasia, 7. Elevated hepatic enzyme levels (ASAT, ALAT >3 times normal value), 8. Serum creatinine level >150 umol/l or estimated clearance of <60%, 9. Serious infections such as hepatitis, pyelonefritis in the past three months or chronic infectious disease such as chronic chest infections with bronchiectasis

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	16-04-2015
Enrollment:	230
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Depomedrol
Generic name:	Methylprednisolone
Registration:	Yes - NL intended use

Product type:	Medicine
Brand name:	Methotrexate
Generic name:	Methotrexate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Placebo
Generic name:	Placebo

Ethics review

Approved WMO Date:	01-12-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	02-03-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	27-03-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	09-07-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	22-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	07-03-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	19-02-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	24-03-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	01-07-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	16-09-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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
EudraCT	EUCTR2014-004472-35-NL
CCMO	NL51205.058.14

Study results

Date completed: 10-10-2024

Results posted: 24-10-2024

Actual enrolment: 236

First publication
24-10-2024