Treat early arthralgia to reverse or limit impending exacerbation to rheumatoid arthritis

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20145

Source
Nationaal Trial Register

Brief title
TREAT EARLIER

Health condition

Rheumatoid Arthritis - Clincally Suspect Artralgia

Sponsors and support

Primary sponsor: Leiden University Medical Centre
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The frequency of clinically detectable arthritis fulfilling the 2010 criteria for RA or of unclassified arthritis with a SJC of more than 2 joints, both persisting for at least 2 weeks, obtained after 2 years.

Secondary outcome

•Percentage of patients in DMARD-free sustained remission after 2 years (DMARD-free sustained remission is the persistent absence of clinically detectable synovitis)

•Percentage of patients with symptom reduction

•Functional ability measured using health assessment questionnaires (HAQ)

•Change in quality of life

•Work loss (absenteeism), presenteeism, work related financial loss

•Changes in Sharp van der Heijde scores on hand and foot radiographs

•Adverse events

•Cost-efficacy

Study description

Background summary

Proof-of-concept study to determine whether intervention with methylprednisolon/MTX vs Placebo in the preclinical phase in symptomatic patients at risk for RA is effective in progression from subclinical inflammation to clinically apparent persistent arthritis.

Study objective

This proof-of-concept study aims to determine whether intervention in the preclinical phase in symptomatic patients at risk for RA is effective in progression from subclinical inflammation to clinically apparent persistent arthritis.

Study design

Every 4 months during 2 years follow-up

Intervention

At the study start all patients will be randomized to treatment with one IM glucocorticoid injection (120 mg methylprednisolone) followed by 12 months of methotrexate or placebo (injection and tablets).

Contacts

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Eligibility criteria

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 type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2015
Enrollment:	230
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	20-10-2014
Application type:	First submission

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
NTR-new	NL4599
NTR-old	NTR4853
Other	METC Leiden Den Haag Delft (LDD) : P14.296 METC LDD

Study results