

Primary prevention of rheumatoid arthritis

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/03/2010	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.janvanbreemen.nl>

Contact information

Type(s)

Scientific

Contact name

Dr D. van Schaardenburg

Contact details

Jan van Breemen Instituut
Dr. Jan van Breemenstraat 2
Amsterdam
Netherlands
1056 AB
+31 (0)20 5896589
d.v.schaardenburg@janvanbreemen.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR133

Study information

Scientific Title

Study objectives

1 - 2 intramuscular injections with 100 mg dexamethasone in persons without arthritis but with elevated serum levels of Rheumatoid Factor (RF) and or anti-Cyclic Citrullinated Peptide (aCCP) will lead to a reduction in antibody concentrations after 6 months and possibly to a lower frequency of rheumatoid arthritis after 5 years, in comparison to no treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, double blinded, placebo controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Rheumatoid arthritis

Interventions

1 - 2 intramuscular injections with 100 mg dexamethason with 6 weeks interval (2nd injection with verum depends on response to first injection) or twice placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Dexamethasone

Primary outcome measure

50% reduction of the concentration of the increased antibodies after 6 months compared to no treatment.

Secondary outcome measures

Frequency of rheumatoid arthritis after 5 years compared to no treatment.

Overall study start date

01/10/2005

Completion date

01/04/2008

Eligibility**Key inclusion criteria**

1. Age 18 - 70 years for RF+, 18+ for aCCP
2. Twice increased Immunoglobulin M (IgM)-RF and/or aCCP with 4+ weeks interval
3. Human Leukocyte Antigen (HLA)-DR Shared Epitope (SE) positive

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

80

Key exclusion criteria

Situations with possible false positive RF:

1. Auto-immune diseases
2. Active infection with hepatitis C or Epstein Barr virus
3. Recent chemotherapy
4. Co-morbidity with decreased life expectancy
5. Corticosteroid use for another disease
6. Contra-indications for corticosteroids: diabetes mellitus, osteoporosis
7. Pregnancy or lactation

Date of first enrolment

01/10/2005

Date of final enrolment

01/04/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Jan van Breemen Instituut

Amsterdam

Netherlands

1056 AB

Sponsor information

Organisation

Jan van Breemen Instituut (Netherlands)

Sponsor details

Dr. Jan van Breemenstraat 2

Amsterdam

Netherlands

1056 AB

Sponsor type

Research organisation

Website

<http://www.janvanbreemen.nl>

ROR

<https://ror.org/00bp9f906>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organization for Health Research and Development (ZonMw) (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2010		Yes	No