Primary prevention of rheumatoid arthritis

Submission date [] Prospectively registered Recruitment status 20/12/2005 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 20/12/2005 Completed [X] Results [] Individual participant data Last Edited Condition category 18/03/2010 Musculoskeletal Diseases

Plain English summary of protocol

Not provided at time of registration

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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Situations with possible false positive RF:

- 1. Auto-immune diseases
- 2. Active infection with hepatitis C or Ebstein 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

Jan van Breemen Instituut (Netherlands)

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes