ISRCTN73232918 https://doi.org/10.1186/ISRCTN73232918

Primary prevention of rheumatoid arthritis

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
18/03/2010

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

Study design
Randomised, double blinded, placebo controlled, parallel group trial

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

Organisation

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