ISRCTN03626626 https://doi.org/10.1186/ISRCTN03626626

Phase IIa trial of interferon-beta-1a (Avonex) in patients with rheumatoid arthritis

Submission date
22/10/2003

Recruitment status
No longer recruiting

Registration date
23/10/2003

Overall study status
Completed

Last Edited
29/08/2007

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

Contact name
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Additional identifiers

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rheumatoid arthritis (RA)

Interventions
Interferon-beta-1a 30 mcg (or matched placebo) intramuscularly each week for 24 weeks.

Intervention Type
Drug

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
Interferon-beta-1a (Avonex)

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/01/2003

Eligibility

Key inclusion criteria
1. Greater than 18 years old who meet the American College of Rheumatology criteria for Rheumatoid Arthritis (RA)
2. Failed at least one currently available Disease Modifying Anti-Rheumatic Drug (DMARD)
3. Active RA with greater than 6 swollen and 6 tender joints
4. C-Reactive Protein (CRP) exceeding 1.0 mg/dl

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2002

Date of final enrolment
01/01/2003

Locations

Countries of recruitment
United States of America

Study participating centre
1000 Welch Road, Suite 203
Palo Alto
United States of America
94304

Sponsor information

Organisation
Biogen Idec Inc. (USA)

ROR
https://ror.org/02jqkb192

Funder(s)

Funder type
Industry

Funder Name
Biogen Idec Inc. (USA)

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	01/01/2004		Yes	No