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

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

Submission date	Recruitment status	[ ] Prospectively registered
22/10/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/10/2003	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/08/2007	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Randomised controlled 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 (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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date

01/01/2002

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
22

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)

Sponsor details
14 Cambridge Center
Cambridge
United States of America
02142

Sponsor type
Industry

ROR
https://ror.org/02jqkb192

Funder(s)

Funder type
Industry

Funder Name
Biogen Idec Inc. (USA)

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	01/01/2004		Yes	No