

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

Submission date 22/10/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/10/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 29/08/2007	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Mark Genovese

Contact details
1000 Welch Road, Suite 203
Palo Alto
United States of America
94304

Additional identifiers

Protocol serial number
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

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