

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

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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