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Multinational randomised controlled clinical trial of etoricoxib in the treatment of rheumatoid arthritis

Submission date
09/05/2002

Recruitment status
No longer recruiting

Registration date
09/05/2002

Overall study status
Completed

Last Edited
15/11/2013

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
Mr Sean Curtis

Contact details
Merck & Co Inc
126 E Lincoln Avenue
Rahway
United States of America
NJ 07065

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
025

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Each site received the approval of its Ethics Review Committee or Institutional Review Board to perform the study.

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

Interventions
1. Etoricoxib 90 mg once daily, naproxen 500 mg twice daily
2. Placebo for 12 weeks

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Etoricoxib, naproxen

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/1999

Completion date
01/06/2000

Eligibility

Key inclusion criteria
1. Patients with rheumatoid arthritis
2. Aged greater than or equal to 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
891

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/11/1999

Date of final enrolment
01/06/2000

Locations

Countries of recruitment
Argentina

Australia

Austria

Brazil

Canada

Chile

Colombia

Costa Rica

France

Germany

Greece

Hong Kong

Israel

Italy

Lithuania

Mexico

New Zealand

Peru

Romania

Singapore

Slovenia

South Africa

Spain

Switzerland

Türkiye

United Kingdom

United States of America

Venezuela

Study participating centre

Merck & Co Inc
Rahway
United States of America
NJ 07065

Sponsor information

Organisation
Merck & Co Inc (USA)

Sponsor details
126 E Lincoln Avenue
Rahway
United States of America
NJ 07065

Sponsor type
Industry

Website
http://www.merck.com

Funder(s)

Funder type
Industry

Funder Name
Merck & Co Inc (USA)

Alternative Name(s)
Merck & Co., Inc., Merck & Co.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

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	22/05/2002		Yes	No