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British study of Risedronate In Structure and symptoms of Knee osteoarthritis

Submission date	Recruitment status	[ ] Prospectively registered
10/02/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/02/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/11/2007	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2000024

Study information

Scientific Title

Acronym

BRISK

Study objectives
To determine the efficacy and safety of risedronate in patients with knee Osteoarthritis (OA). The British study of Risedronate In Structure and symptoms of Knee osteoarthritis (BRISK), a 1-year prospective, double-blind, placebo-controlled study enrolled patients (40 - 80 years) with mild-to-moderate medial compartment knee OA. The primary aims were to detect differences in symptoms and function. Patients were randomised to once-daily risedronate (5 mg or 15 mg) or placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The subjects gave their written, informed consent before entering the study, which was conducted in accordance with the International Conference on Harmonization (ICH) guidelines for Good Clinical Practice (GCP) and was approved by the UK Multicentre Research Ethical Committee (MREC).

Study design
Prospective, double-blind, placebo-controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteoarthritis (OA)

Interventions
Patients were randomised to:
1. 5 mg of Risedronate
2. 15 mg of Risedronate
3. Placebo

Patients were treated once daily for one year.

Knee radiographs were performed at baseline and at one year, urine and serum samples were collected at baseline and at months three, six and twelve and the Western Ontario and McMaster Universities OA Index was also performed.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Risedronate

Primary outcome(s)
The outcome instrument for assessment of OA symptoms was evaluation of risedronate efficacy on symptoms of OA was the Western Ontario and McMaster Universities (WOMAC) OA index. The visual analogue scale (VAS) of the index was used, in which patients assessed each question using a 100 mm scale, with a higher score representing greater symptom severity. The total index score for the signal knee corresponded to the weighted composite of the 24 question scores standardised to a 100 point scale; scores were also determined for the subscales of pain (five questions), stiffness (two questions) and physical function (17 questions).

The outcome measure for assessment of joint structural changes was mean change from baseline in minimum JSW of the medial compartment of the knee. Radiographs of the knee were taken at baseline and at 1 year using a standardised radiographic method with fluoroscopic positioning of the joint in a semi-flexed position.

Key secondary outcome(s))
Other symptom outcome measures included a Patient Global Assessment (PGA) of disease, consumption of pain medication and the use of walking aids. For the PGA, patients answered the following question using a VAS: Considering all the ways your OA affects you, how have you been in the last 48 hours? Results for the question were expressed as values on a 0 - 100 mm scale.

Completion date
01/01/2004

Eligibility

Key inclusion criteria
1. Male and female subjects aged 40 - 80 years
2. Mild-to-moderate medial-compartment knee OA
3. Diagnosed according to the clinical and radiological criteria of the American College of Rheumatology
4. OA in at least one knee, designated as the signal knee, was required to meet the following clinical and radiographic criteria.

Clinical inclusion criteria:
1. Presence of daily knee pain for at least 1 month out of 3 months prior to the study
2. At least one of the following:
2.1. Age greater than 50 years old
2.2. Morning knee stiffness of less than 30 minutes
2.3. Knee crepitus

Radiographic criterion for inclusion:
1. A Joint-Space Width (JSW) of between 2 - 4 mm in the medial tibiofemoral compartment in the semi-flexed Anterior-Posterior (AP) view
2. A requirement for a narrower width than in the lateral compartment of the same knee
3. Patients were also required to have at least one osteophyte in either the medial or lateral compartments of the tibiofemoral joint

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. The presence of rheumatic diseases that could be responsible for secondary OA
2. Use of intra-articular hyaluronic acid in the signal knee
3. Knee injury or diagnostic arthroscopy of the signal knee in the 6 months prior to enrolment
4. History of knee surgery (including arthroscopy requiring an incision of internal joint components) in the signal knee at any time
5. Intra-articular corticosteroids in the 3 months preceding enrolment
6. The presence of non-OA causes of knee pain in the signal knee (e.g. anserine bursitis, fibromyalgia and osteonecrosis)
7. Use of bisphosphonates within 12 months prior to enrolment

Date of first enrolment
01/01/2003

Date of final enrolment
01/01/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Consultant Rheumatologist
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Sponsor information

Organisation
Procter and Gamble Pharmaceuticals (USA)

ROR

https://ror.org/04dkns738

Funder(s)

Funder type
Industry

Funder Name
Procter and Gamble Pharmaceuticals (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	24/03/2005		Yes	No