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Analgesic action of acetaminophen in symptomatic osteoarthritis of the knee: a randomised controlled study

Submission date
09/05/2005

Recruitment status
No longer recruiting

Registration date
10/05/2005

Overall study status
Completed

Last Edited
15/02/2008

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym
Knee study

Study objectives
The study was designed to investigate the analgesic effects and mechanisms of acetaminophen (paracetamol) in symptomatic osteoarthritis (OA) of the knee.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the local ethical committee (Kantonale Ethikkommission, Spezialisierte Unterkommission fur Spezialfa cher) (ref: 343)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Osteoarthritis of the knee

Interventions
After washout of earlier OA medications, patients were randomly allocated into two groups treated with either acetaminophen up to 4 g per day (n = 10, age 60-77 years) or rofecoxib 25 mg per day (n = 10, age 48-80 years) for 3 months.

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Acetaminophen (paracetamol), rofecoxib

Primary outcome measure
The functional status of the knee joint was assessed by the Western Ontario McMaster Universities Osteoarthritis (WOMAC) questionnaire in German. Visits and measurements were scheduled upon entry (T0), month 1 (T1) and month 3 (T3).

Secondary outcome measures
The intensity of joint pain was evaluated by 100-mm visual analogue scale (VAS) at rest. Visits and measurements were scheduled upon entry (T0), month 1 (T1) and month 3 (T3).

Overall study start date
01/11/2001

Completion date
31/03/2002

Eligibility

Key inclusion criteria
Patients and healthy subjects: 20 patients fulfilled the American College of Rheumatology criteria for knee OA accompanied with joint pain (visual analogue scale [VAS] ≥60) were recruited to the study. For control, blood from 20 age and gender-matched healthy subjects was obtained from a local blood bank, the Blutspenderdienst Zürich. All patients signed the informed consent.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Secondary OA as a consequence of inflammation, gout, pseudogout or tumour
2. Kidney insufficiency
3. OA-influencing concomitant diseases
4. Drug medication with opioids

Date of first enrolment
01/11/2001

Date of final enrolment
31/03/2002

Locations

Countries of recruitment
Switzerland

Study participating centre
Department of Rheumatology and Institute of Physical Medicine
Zurich
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8091

Sponsor information

Organisation
Merck Sharp and Dohme (MSD) (Switzerland)

Sponsor details
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Sponsor type
Industry

ROR
https://ror.org/009nc9s30

Funder(s)

Funder type
Industry

Funder Name
Merck Sharp and Dohme (MSD) (Switzerland) - gave a Medical School Grant in 2001 to perform the study, and provided the drug Vioxx (rofecoxib). The acetaminophen drugs and the other research costs were paid for from the grant.

Funder Name
University Hospital Zurich (Switzerland) - provided the infrastructure

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	01/06/2006		Yes	No