

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

Submission date 09/05/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/05/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/02/2008	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

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 für Spezialforschung) (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

Switzerland

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