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Which treatment for low back pain? A factorial randomised controlled trial comparing intravenous analgesics with oral analgesics in the emergency department and a centrally acting muscle relaxant with placebo over three days

Submission date
18/10/2001

Recruitment status
No longer recruiting

Registration date
18/10/2001

Overall study status
Completed

Last Edited
10/03/2008

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
BAPA

Study objectives
Objectives:
1. To compare the effectiveness of intravenous non-steroidal analgesics with oral non-steroidal analgesics for acute treatment in the Emergency Department (ED) (Stage 1)
2. To compare the effectiveness of either arm with the effectiveness in those patients who refused to be randomised but agreed to participate in the patient preference trial with the treatment of their choice
3. To compare the effectiveness of a centrally active muscle relaxant with placebo given for three days after presentation to the ED (Stage 2)
4. To compare the effectiveness of either arm with the effectiveness in those patients who refused to be randomised but agreed to participate in the patient preference trial with the treatment of their choice

Ethics approval required
Old ethics approval format

Ethics approval(s)
The protocol was approved by the ethics committee of the Vienna Medical Faculty.

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
Back pain

Interventions
Stage 1 intervention:
Patients are randomised to oral diclofenac (150 mg) plus intravenous placebo or oral placebo plus intravenous diclofenac (75 mg) in a double blind fashion. The dose of diclofenac for oral administration has to be twice the intravenous dose because of a 50% first pass elimination of the active ingredient. Patients will be assessed after 90 minutes (this is the average time needed for the intravenous administration of an infusion containing analgesics).

The primary endpoint at 90 minutes is pain assessed with a visual analogue scale (VAS), secondary endpoint is the Roland Morris disability questionnaire (RMDQ), and the quality of life score as measured by the 36-item short form health survey (SF-36). If patients still have severe pain further intravenous therapy should be given according to the discretion of the treating physician.

Stage 2 intervention:
After the first step patients are randomised to oral diclofenac (2 x 100 mg/day or 1 x 100 mg/day if bodyweight is less than 60 kg) and the oral muscle-relaxant tizanidin (Sirdalud® 3 x 2 mg, Novartis Pharma AG, Basel, Switzerland) over three days versus oral diclofenac (2 x 100 mg/day or 1 x 100 mg/day if bodyweight is less than 60 kg) plus oral placebo in a double blind fashion. Patients with a history of gastric pain, suggestive of ulcer or non-ulcer dyspeptic disease will receive a proton pump inhibitor for gastric protection (pantoprazol 1 x 40 mg/day, Pantoloc® Byk Pharma Österreich).

Patients who refuse randomisation but agree to participate in the patient preference trial will receive the treatment of their choice (this refers to both stages). Treatment and follow-up will be identical in the randomised and patient preference groups.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Diclofenac, tizanidin (Sirdalud®), pantoprazol

Primary outcome measure
Pain assessed by means of the VAS. For stage one, the VAS is evaluated immediately before and 90 minutes after treatment, for stage two, the VAS is evaluated on day four.

Secondary outcome measures
1. The Roland Morris disability questionnaire (RMDQ)
2. 36-item short form health survey (SF-36)

Stage one is evaluated immediately before treatment by personal interview, then, for stage two, the RMDQ and the SF-36 is evaluated four days after enrolment. Patients will be interviewed by telephone using the structured format of the questionnaires of RMDQ and SF-36.

Overall study start date
01/01/2001

Completion date
31/12/2003

Eligibility

Key inclusion criteria
1. Lower back pain localised between 12th rib and gluteal fold
2. Duration of pain of the current period less than seven days
3. Attending the Department of Emergency Medicine at the Vienna General Hospital because of low back pain
4. Agree to be randomised or agree to be included in the patient preference trial
5. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
230

Key exclusion criteria
1. History:
1.1. Ingestion of any analgesic drug within 6 hours
1.2. Direct impact trauma
1.3. History of cancer
1.4. Unexplained weight loss (greater than 10 kg within three months)
1.5. Current injection drug use
1.6. Any known chronic infection, such as hepatitis, human immunodeficiency virus (HIV), tuberculosis
1.7. Immunosuppressive therapy (such as systemic corticosteroids, ciclosporine, or such)
1.8. Organ transplantation
1.9. History of inflammatory arthritis of large joints
1.10. Current bowel or bladder dysfunction
1.11. Involved in litigation
1.12. Alcohol abuse
1.13. Aged less than 19 and greater than 65 years
1.14. Current abdominal problems (epigastric pain)
1.15. A history of gastric or duodenal ulcer
1.16. A history of severe renal or hepatic insufficiency or severe coronary insufficiency
1.17. Allergies against any non-steroidal analgesics (NSA) or tizanidin
2. Physical examination:
2.1. Fever greater than 38°C

2.2. Sensory or motor deficit in lower limb
2.3. Lasegue positive greater than 60°
2.4. Pregnancy: to be ruled out by a commercially available and routinely used urine pregnancy test
2.5. Urinary tact infection: to be ruled out by a commercially available and routinely used urine dip stick test; infection is assumed if nitrite and leukocytes test positive
3. Communication problems:
3.1. Patients who appear not to be able to understand the information provided to give informed consent for participation in this trial because of mental or physical handicaps. It is the duty of the enrolling physician to decide whether a potential participant has sufficient language skills to understand the information provided or to communicate that she/he understands.
3.2. Patients who appear not to be able to understand the information provided to give informed consent for participation in this trial because of language barriers. Those who need an interpreter to communicate with the treating physician are certainly ineligible. Otherwise it is the duty of the enrolling physician to decide whether a potential participant has sufficient language skills to understand the information provided.

Date of first enrolment
01/01/2001

Date of final enrolment
31/12/2003

Locations

Countries of recruitment
Austria

Study participating centre
Universitätsklinik für Notfallmedizin
Wien
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Sponsor information

Organisation
Medical University of Vienna (Austria)

Sponsor details
Department of Emergency Medicine
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Sponsor type
University/education

Website
http://www.univie.ac.at/indexengl.html

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
University/education

Funder Name
The Medical-Scientific Fund of the Mayor of Vienna (Medizinisch-Wissenschaftlicher Fonds des Bürgermeisters der Bundeshauptstadt Wien) (Austria) - protocol submitted for funding, as of 17 /10/2001) there is no decision

Funder Name
Novartis Pharma GmbH (Austria) - covering patient insurance

Funder Name
Byk Pharma (Austria) - providing pantoprazol

Funder Name
Novartis Pharma and Byk Pharma will not be involved in data collection, analysis or data interpretation.

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?
Protocol article	Study protocol	01/03/2001		Yes	No