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Cost-effectiveness analysis of oral paracetamol and ibuprofen for treating pain after soft tissue limb injuries: double-blind, randomised controlled trial

Submission date
06/09/2007

Recruitment status
No longer recruiting

Registration date
19/10/2007

Overall study status
Completed

Last Edited
15/07/2021

Condition category
Injury, Occupational Diseases, Poisoning

[ ] 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

ClinicalTrials.gov (NCT)
NCT00528658

Protocol serial number
HKCEM06-07/DG2041095

Study information

Scientific Title
Cost-effectiveness analysis of oral paracetamol and ibuprofen for treating pain after soft tissue limb injuries: double-blind, randomised controlled trial

Study objectives
We hypothesise firstly that paracetamol 1 g and ibuprofen 400 mg administered orally for soft tissue injuries have equal analgesic efficacy; secondly that paracetamol has less adverse effects than ibuprofen; and that when all additional health care related costs are taken into account, that paracetamol will be the more cost-effective option.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Joint Chinese University of Hong Kong - New Territories East Cluster (CUHK-NTEC) Clinical Research Ethics Committee on the 8th October 2004 (ref: CRE-2004.266-T).

Study design
Prospective, double-blind, randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Soft Tissue Injuries

Interventions
Arm 1: Paracetamol 1 g four times daily (qid) and ibuprofen placebo equivalent to 400 mg three times daily (tid)
Arm 2: Paracetamol placebo equivalent to 1 g qid and ibuprofen 400 mg tid
Arm 3: Paracetamol 1 g qid and ibuprofen 400 mg tid

Treatment will continue for three days, follow-up will continue for 30 days.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Paracetamol, ibuprofen

Primary outcome(s)
Analgesic efficacy both at rest and with movement at 72 hours.

Key secondary outcome(s))
1. Presence, frequency and duration of adverse effects at 30 days
2. Cost-effectiveness analysis at 30 days
3. Patient satisfaction with analgesia at 30 days

Completion date
31/12/2007

Eligibility

Key inclusion criteria
All patients greater than 16 years presenting to the Emergency Department (ED) with isolated soft tissue injury without significant fracture between 9 am to 5 pm, Monday to Friday.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
782

Key exclusion criteria
Patients will be excluded if there is:
1. A history of peptic ulceration or haemorrhage
2. Recent anticoagulation
3. Pregnancy
4. Adverse reaction to paracetamol or ibuprofen
5. Renal or cardiac failure
6. Hepatic problems
7. Rectal bleeding
8. Chronic Non-Steriodal Anti-Inflammatory Drug (NSAID) consumption
9. Asthma
10. Chronic obstructive pulmonary disease
11. Chronic pain syndromes
12. Prior treatment with analgesia for the same injury

Patients will also be excluded if they have a physical, visual or cognitive impairment making use of the visual analogue scale unreliable.

Date of first enrolment
01/01/2005

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Hong Kong

Study participating centre
Trauma and Emergency Centre
Shatin
Hong Kong
NT

Sponsor information

Organisation
Chinese University of Hong Kong (Hong Kong)

ROR
https://ror.org/00t33hh48

Funder(s)

Funder type
University/education

Funder Name
Chinese University of Hong Kong (Hong Kong) (Direct Grant: 2041095)

Funder Name
Hong Kong College of Emergency Medicine (Hong Kong) (Grant: 2006-07)

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		06/02/2018	15/07/2021	Yes	No