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A clinical trial to compare subcutaneous injection versus intravenous injection of tramadol for extremities injuries with moderate pain in the emergency department

Submission date
23/03/2018

Recruitment status
No longer recruiting

Registration date
05/04/2018

Overall study status
Completed

Last Edited
05/04/2018

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background of study and aims
Pain is the leading cause of visits to any emergency department and a large percentage of it is caused by injuries to the limbs such as sprains, bruising of skin and soft tissues, ligament injuries, muscle pain and fractures. The recommended choice of pain relief medication for patients with limb injuries and moderate pain is tramadol, as it does not interfere with wound healing during the first 24 to 48 hours of injury. Tramadol is commonly administered to patients by the intravenous route, meaning a needle and cannula have to be inserted into the patient's vein usually on the arm (that is not injured). There is a possibility of delay in administering pain relief medication this way if there is difficulty in finding a suitable vein. The choice for administering any medications into the vein directly is because of faster onset of action due to the drug being circulated in blood more rapidly. Tramadol can also be administered by subcutaneous injection, meaning using a needle to administer the drug just under the skin. This uses a smaller and shorter needle, similar to how insulin is administered for patients with diabetes, and therefore tolerated well by most patients. Unlike the intravenous way, subcutaneous injection does not require leaving a cannula in the patient's skin after the drug has been administered. This reduces the risks of infection and pain associated with a sited cannula in the patient's vein. Although it takes longer for the drug to reach the blood circulation, recent studies in populations of patients undergoing surgery receiving subcutaneous tramadol showed that it was effective at achieving significantly reduced pain within 30 minutes. Another benefit from subcutaneous tramadol is that it is associated with less side effects such as nausea and drowsiness compared to intravenous tramadol due to slower absorption into the blood stream. Comparison between subcutaneous tramadol and intravenous tramadol has not been studied before in the population of emergency department patients with moderate pain caused injuries to their extremities. Therefore this study aims to compare the effectiveness of both methods of injection in terms of pain relief, and also compare the occurrence of side effects, pain associated with intravenous cannulation and subcutaneous injection, and patient's overall satisfaction.

Who can participate?
Adult patients for 18 years and above.

What does the study involve?
Eligible patients based on specific criteria will be approached for recruitment into the study. Consent will be taken from patients after information about the study is explained. Patients then are allocated into receiving either intravenous tramadol or subcutaneous tramadol. Patients will be assessed by the emergency department doctors as per standard practice and all necessary investigations performed. Patients will be asked to rate their pain intensity on a scale of 0 to 10 (0 means no pain and 10 means the most severe pain as perceived by the patient). The pain scores are documented before the administration of tramadol, and at 15 minutes interval after administration of tramadol until pain relief is achieved. Safety of patients is monitored during the study and symptoms or signs of the patients are recorded. The treating doctors are allowed to administer additional pain relief medication and any other treatment required at any time if they feel indicated.

What are the possible benefits and risks of participating?
The possible benefits are that patients could have shorter waiting time before administration of pain relief medication, better pain relief and lesser side effects (depending on the route of tramadol administration). Possible risks are slower pain relief depending on the route of tramadol administration. Side effects are usually rare, but patients are more frequently monitored as to follow the study protocol.

Where is the study run from?
University of Malaya Medical Centre Emergency Department

When is the study starting and how long is it expected to run for?
September 2017 to March 2019.

Who is funding the study?
None.

Who is the main contact?
Dr. Aida Bustam (aidabustam@um.edu.my)

Contact information

Type(s)
Scientific

Contact name
Dr Aida Bustam

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2017613-5340

Study information

Scientific Title
Subcutaneous versus intravenous tramadol for extremities injuries with moderate pain in the emergency department: a randomised controlled non-inferiority trial

Study objectives
The non-inferiority null hypothesis is that a therapeutic difference in terms of mean pain score of more than 0.8 (0- to 10-point scale) exists between the two treatment groups (subcutaneous versus intravenous tramadol) at endpoint. The non-inferiority alternative hypothesis is that the difference in terms of mean pain score is not more than 0.8 between the two treatment groups at endpoint. If the condition of non-inferiority is satisfied, then the superiority of subcutaneous tramadol over intravenous tramadol could be assessed in a second test of the conventional null hypothesis of no difference between the two treatments.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Malaya Medical Centre Medical Research Ethics Committee, 25/10/2017, 2017613-5340

Study design
Single-centre randomised non-inferiority parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Pain associated with extremities injuries

Interventions
198 patients are randomly assigned to two groups using a stratified block randomisation sequence method. Patients are stratified by baseline pain score (pre-intervention pain score of 4, 5 or 6 (moderate pain) using verbal numerical rating scale) to achieve a similar distribution between intervention groups. One group receives a single dose of 50 mg of tramadol by subcutaneous injection. Subcutaneous injection is administered using a hypodermic syringe at the periumbilical area, similar to the technique of insulin administration. Another group receives a single dose of 50 mg of tramadol by intravenous administration. The site of peripheral cannula for the intravenous administration is at the discretion of the treating doctor.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Pain score, as measured using verbal numerical rating scale, at 30 min after the administration of tramadol

Secondary outcome measures
1. Time from administration of tramadol to pain relief (or to decision to administer rescue analgesia)
2. Pain score associated with subcutaneous injection and intravenous cannulation
3. Incidence of any local or systemic side effects
4. Need for rescue analgesia
5. Need for anti-emetic
6. Patient's overall satisfaction using a 5-point Likert scale

Overall study start date
01/09/2017

Completion date
31/03/2019

Eligibility

Key inclusion criteria
1. Patients voluntarily sign the informed consent form
2. Patients presenting with extremities injuries - defined as injuries to the upper limbs including the shoulders, and injuries to the lower limbs excluding the hip

3. Soft tissue injuries or suspected soft tissue injuries (skin abrasions, sprains, strains, ligament injuries, muscle injuries)
4. Closed fracture or suspected closed fracture
5. Moderate pain (pain score of 4, 5 or 6 using verbal numerical rating scale)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
198

Key exclusion criteria
1. Patients with open fractures as they will require procedural sedation for early reduction
2. Patients with laceration wounds as they will require local anaesthesia for wound suturing
3. Patients who will require admission
4. History of allergy or suspected allergy to tramadol
5. Pregnant patients
6. Patients with known liver disease
7. Patients who had consumed or had received any analgesia prior to presentation to the emergency department
8. Patients who are taking analgesia for other pathology

Date of first enrolment
01/03/2018

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Malaysia

Study participating centre
University of Malaya Medical Centre Emergency Department
Kuala Lumpur
Malaysia
59100

Sponsor information

Organisation
University of Malaya

Sponsor details
Faculty of Medicine
University of Malaya
Kuala Lumpur
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59100

Sponsor type
University/education

Website
http://medicine.um.edu.my

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in an indexed peer-reviewed journal.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Available on request