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Study comparing a regional leg block vs. local anaesthetic infiltration for leg donor sites in burns patients - pain scores and analgesic requirements

Submission date
22/03/2016

Recruitment status
No longer recruiting

Registration date
04/05/2016

Overall study status
Completed

Last Edited
17/08/2018

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
In the UK about 250,000 people sustain burn injuries each year. Of these, 175,000 attend accident and emergency departments and 13,000 need to be admitted to hospital. During treatment patients might need to be taken to theatre for the burn wound to be cleaned thoroughly and also to apply a skin graft to the wound. This will usually be done under a general anaesthetic. The skin graft is a piece of skin taken from the patient's unburnt skin in order to cover the burn wound and promote healing. This piece of skin is usually taken from the thigh. The amount of skin that is taken will depend on the size of the burn that needs to be covered. The site that the skin graft is taken from can be a cause of more pain than the original burn. In order to prevent this pain the surgeons sometimes use a local anaesthetic to make the skin numb. Sometimes the anaesthetists might give a local anaesthetic block called the fascia iliaca compartment block to prevent pain. This involves injecting local anaesthetic drugs into the front of the thigh near the groin crease. It is a single injection and the exact place of injection near the groin crease is guided by using ultrasound. This injection of local anaesthetic blocks the nerves that detect sensation from the thigh and thereby give pain relief. We wish to find out whether this block (fascia iliaca compartment block) is better at providing pain relief to the donor site (where the skin graft was taken) than local anaesthetic infiltration. We also want to find out if this block might provide a longer period of pain relief.

Who can participate?
Adult patients with burns undergoing skin grafts where the donor site is the thigh.

What does the study involve?
Participants are randomly allocated to be treated with either fascia iliaca compartment block or local anaesthetic infiltration. Participants are offered addition pain relief medications after the surgery, if required. All other treatment is the same as standard practice. Participants' pain and use of painkillers is assessed.

What are the possible benefits and risks of participating?
The fascia iliaca block is a very safe local anaesthetic block, which has been used for many years to provide pain relief to problems in the thigh region such as femoral fractures and hip fractures. It has also been used in burn centres to provide pain relief to the burn donor site. The risk is very low. Those patients who receive a block will find that their leg is numb and weak for some time after the block, making walking difficult for a few hours. Most of the time the patient would be kept on bed rest anyway for the grafts to heal. There is also a very small risk of infection and nerve damage but these risks are further minimised because we do this block under ultrasound guidance. The risk of nerve damage is small. The block when performed correctly is not in the path of any major nerve. Local anaesthetic infiltration around the donor site is also a long-standing technique that is used and side effects are rare. The patient will be carefully monitored in theatre and the ward regardless of the type of pain relief that they receive.

Where is the study run from?
Mid Essex Hospital Services NHS Trust (UK)

When is the study starting and how long is it expected to run for?
June 2014 to May 2017

Who is funding the study?
Mid Essex Hospital Services NHS Trust (UK)

Who is the main contact?
1. Dr Malka Sandunmalee Liyanage
2. Dr Peter Berry

Contact information

Type(s)
Public

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Protocol serial number
R&D 1012

Study information

Scientific Title
Study of fascia iliaca blocks vs. conventional local anaesthetic infiltrations for leg donor sites in burns patients – pain scores and analgesic requirements

Acronym
FICB

Study objectives
Patients with burns often require skin grafts to the site of the burn. A common place to take the skin graft from is the side of the thigh. It is often seen that the pain from the site where the skin graft is taken is more intense than that of the burn wound itself.

Fascia Iliaca Compartment Block (FICB) is a safe and simple method of giving local anaesthetic agents to the groin to provide pain relief for surgery to the thigh and hip. The local anaesthetic agents cause numbness by blocking the nerves supplying the hip and the thigh. It has been used to provide pain relief for patients with fractures of the neck of femur in emergency rooms for a long period of time and has a demonstrated safety profile.

Currently the most common method for providing pain relief after surgery to the skin graft is by infiltration of local anaesthetic to the tissues via multiple injections.

The purpose of the study is to find out if there is a difference in the pain relief obtained by the patients depending on whether they have a FICB or the direct local anaesthetic infiltration. This would be measured by the amount of oral pain relief medications they need postoperatively and also their level of pain as determined by a simple pain score.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England - Cambridgeshire and Hertfordshire Research Ethics Committee, 09/02/2016, 15/EE/0066

Study design
Prospective partially blinded randomised controlled study

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Pain in the donor sites of burns patients

Interventions
Patients coming to the burns or plastics theatres for skin grafting and where the graft is to be taken from the thigh would be included after applying the exclusion criteria. Burn size would be less than 7% and donor site >0.5% TBSA in order to meet the inclusion criteria. The anaesthetist in charge of the list on that day would have the discretion to either include or exclude the patient in the study.

If all criteria are satisfied, the patient would be consented for both the block and local infiltration at the same time as consenting to take part in the study.

Randomisation would be by random number tables (generated by Random.org) and sealed numbered envelopes to be picked up by the anaesthetist. These would state the arm of the study to which the patient would belong.

In those patients who are randomised to the block arm, the fascia iliaca block would be performed under ultrasound guidance. The block would be performed using 0.8 ml/kg 0.25% levobupivicaine as the local anaesthetic dosing regimen, with a maximum local anaesthetic volume of 40 ml.

For those patients randomised to local infiltration, the surgeons would directly infiltrate the same local anaesthetic regimen to the donor site, after the skin graft had been taken. The levobupivacaine may contain 1:200,000 adrenaline according to surgical preference, in order to limit blood loss.

Intraoperatively, the patient would have a target controlled infusion of Remifentanil 3-5 ng/ml, titrated according to the responsible anaesthetists' judgement. Paracetamol 1g and Diclofenac 75 mg would be given intravenously if not contraindicated. Morphine 0.1 mg/kg-0.3 mg/kg will be given towards the end of the procedure. All other anaesthetic factors would be determined by the responsible anaesthetist. Should further analgesia be felt necessary, the responsible anaesthetist would document the rationale in the study proforma.

A standardised postoperative regimen of regular Paracetamol plus Ibruprofen if not contraindicated would be prescribed. Breakthrough analgesia in the form of Oromorph 0.2 mg /kg (rounded to the nearest 10 mg) m, max 1 hourly would also be available. Any pre-existing analgesia for the burn pain, for example Gabapentin or Clonidine, would be continued. Naloxone 100mcg prn would be prescribed in case of opiate toxicity.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The use of opiate painkillers at 24 and 48 hours. Our chosen threshold for a clinically significant difference will be a 20% difference in opiate usage at 24 and 48 hours between patients receiving fascia iliaca blocks, compared to those receiving the same volume and concentration of local anaesthetic via direct infiltration into the skin.

Key secondary outcome(s))
1. Maximum pain score 6 hours after surgery, first post-operative day and second post-operative day
2. Time to first dose of opiate medication after discharge from recovery
3. Patient satisfaction with post-operative analgesia, assessed at 24 and 48 hours
4. The density and duration of muscle weakness associated with fascia iliaca blocks by the use of bromage scores in the first and second post-operative day (does not include patients who are not allowed to move the grafted leg)

Completion date
01/12/2018

Eligibility

Key inclusion criteria
Adult patients with burns admitted to the burns service at St. Andrews with <7% burns and undergoing split skin grafts where the donor site will be the anterolateral thigh only and expected to be at least 0.5% total body surface area (TBSA).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients <16 years old
2. Patients unable to comment on the pain scores effectively e.g., unable to speak English
3. Patients unable to give informed consent e.g., dementia
4. Patients refusing consent for the fascia iliaca block
5. Patients requesting a particular form of analgesia
6. Patients previously on treatment for chronic pain conditions
7. Patients from whom multiple donor sites are anticipated
8. Patients with renal impairment sufficient to alter the planned opiate dosage
9. Patients with a current or previous history of opiate abuse

Date of first enrolment
01/03/2016

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Mid Essex Hospital Services NHS Trust
Broomfield Hospital
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Sponsor information

Organisation
Mid Essex Hospital Services NHS Trust (UK)

ROR
https://ror.org/0280r7h11

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Mid Essex Hospital Services NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes