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The effect of bilateral ultrasound-guided maxillary nerve block on pain relief following cleft palate repair surgery

Submission date 16/07/2019	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 18/07/2019	**Overall study status** Completed	
Last Edited 01/06/2021	**Condition category** Signs and Symptoms	

Plain English summary of protocol

Background and study aims
Cleft lip and/or cleft palate occurs in about 1 in 700 births worldwide, although the incidence varies widely across populations. The incidence in Ireland is about 1 in 625 live births, of which half are isolated cleft palate and half are cleft lip with or without cleft palate. Cleft plate repairs can be painful after surgery and satisfactory pain management can be challenging. Injection of long-acting local anaesthetic into the palatal tissues during surgery is routinely used in order to reduce the need for opioid medication after surgery. However, a local anaesthetic nerve block may provide more effective pain relief after surgery, reducing the need for opioids, allowing earlier feeding and discharge from recovery and hospital and reducing the use of intensive care or high dependency facilities. The aim of this study is to determine if pain relief is better with both general anaesthetic and local anaesthetic or general anaesthetic alone in cleft palate repair surgery.

Who can participate?
Patients who underwent cleft palate surgery with general anaesthetic and local anaesthetic or just general anaesthetic

What does the study involve?
Data is collected on patients who have already undergone cleft palate surgery and had general anaesthesia and local anaesthetic block. Data includes pain scores, analgesia requirements during and after surgery, adverse effects of regional blocks, time to first feed, time to discharge from recovery and time to discharge from hospital. This data is compared with similar data available for a previous group of patients who had palate repair before the introduction of local anaesthetic.

What are the possible benefits and risks of participating?
This study will provide evidence that local anaesthetic is beneficial or that it is not as good as believed. Use of local anaesthetic may help to reduce pain, the need for opioids, time to first

feed, and discharge times by providing more effective pain relief. It may also allow savings in hospital costs by reducing the requirements for higher levels of care and allowing earlier discharges. There are no risks in participating in study as surgeries have already been carried out.

Where is the study run from?
Our Lady's Children's Hospital Crumlin (Ireland)

When is the study starting and how long is it expected to run for?
September 2017 to January 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1

Study information

Scientific Title

Bilateral maxillary nerve blocks via a suprazygomatic approach to the pterygopalatine fossa for pain relief in cleft palate repairs: a comparative study of general anaesthesia combined with bilateral maxillary nerve blocks via a suprazygomatic approach to the pterygopalatine fossa with 0.25% levobupivacaine, versus general anaesthesia alone on pain management in cleft palate repairs

Study objectives

Current hypothesis as of 04/05/2021:
A previous prospective-retrospective audit of suprazygomatic blocks versus GA and recent randomised control trial of bilateral maxillary blocks (PPMB) via the suprazygomatic approach has provided evidence that PPMB is safe and has been shown to reduce opioid consumption post-operatively. This block has been implemented by some of the anaesthetic consultants in Our Ladys Childrens Hospital Crumlin already, given this evidence. Implementation of this block has been found to have positive post-operative pain effects, although these effects have not been studied. Both consultant anaesthetists and surgeon believe this block is safe and is an improvement on existing techniques with beneficial effects on pain relief postoperatively. It is therefore not possible to conduct a randomized control trial, as there is not sufficient equipoise to withhold this block from a control group. The researchers will therefore conduct a two-stage study retrospectively. The first stage, will be a service review where we will find the historic opioid use the (primary outcome) in unselected cleft palate repairs without pterygopalatine fossa maxillary nerve block NoPPMB. The second part was an analysis of a change of practice without randomisation in which the same primary and secondary outcome measurements were made after introduction of bilateral ultrasound guided PPMB.

Hypothesis: Bilateral ultrasound guided PPMB with 0.3 ml/kg of 0.25% levobupivacaine will have significantly decreased postoperative intravenous morphine consumption, when compared to a NoPPMB group, in paediatric patients following cleft palate surgery.

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Previous hypothesis:
A previous prospective-retrospective audit of suprazygomatic blocks versus GA4 and a recent randomised control trial of bilateral maxillary blocks via the suprazygomatic approach has provided evidence that PPMB is safe and has been shown to reduce opioid consumption post-operatively. This block has been implemented by some of the anaesthetic consultants in Our Ladys Childrens Hospital Crumlin already, given this evidence. Implementation of this block has been found to have positive post-operative pain effects, although these effects have not been audited. Both Consultant Anaesthetists and Surgeons believe this block is safe and is an improvement on existing techniques with beneficial effects on pain relief postoperatively. It is therefore not possible to conduct a randomized control trial, as there is not sufficient equipoise to withhold this block from a control group. The researchers will therefore conduct a two-stage study. The first stage, the retrospective part, will be a service review where the researchers will use audit techniques and mathematical analysis to find the historic opioid use, time to discharge and time to 1st feed in unselected palate repairs without bilateral PPMB. The second part will be a prospective analysis of a change in practice without randomization in which the researchers will make the same measurements after the introduction of bilateral PPMB.

Hypothesis: Bilateral PPMB with 0.25% levobupivacaine has no effect on pain scores, intra- and post-operative analgesic requirements, time to first feed or discharge times.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 11/09/2018, Ethics (Medical Research) Committee (Our Lady's Hospital Crumlin, Dublin D12 N512 Ireland; Tel: +353 (0)1 409 6307/6243)

Study design
Two-stage study: retrospective group and prospective group since regional block introduction

Primary study design
Observational

Secondary study design
Two-stage study: retrospective observational service evaluation

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cleft palate repair pain management

Interventions
The researchers will be retrospectively recording data on primary and secondary outcomes in a group who underwent general anaesthetic and local anaesthetic and those who just had general anaesthetic in a group who underwent cleft palate surgeries.

Data will be collected intraoperatively in recovery, on the ward until discharge and at the 1st outpatient appointment, which is roughly 6 weeks post-surgery.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 04/05/2021:
Opioid consumption up to 48 h postoperatively

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Previous primary outcome measure:
Postoperative opiate consumption at 48 hours and to discharge, measured from patients' medical records

Secondary outcome measures
Current secondary outcome measures as of 04/05/2021:
Measured from patients' medical records:
1. Time to first analgesic requirement
2. Time to discharge from recovery and hospital

3. Block problems
4. Airway complications
5. Postoperative nausea and vomiting

Other data collected:
6. Type of general anaesthetic
7. Surgical infiltration
8. Unplanned admission to ICU or HDU
9. Non-opiate post operative analgesia
10. Intra-operative antibiotics and fluids

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Previous secondary outcome measures:
Measured from patients' medical records:
1. Postoperative pain scores assessed by FLACC up to 48 hours
2. Intra- and post-operative analgesia requirements until discharge (mg)
3. Time to first analgesic requirement
4. Time to first feed (time taken to establish milk feed following an initial trial of water or milk)
5. Time to discharge from recovery and hospital
6. Adverse events (to discharge and at 1st 6-week outpatient appointment)
7. Block problems (to discharge and at 1st 6-week outpatient appointment)
8. Postoperative nausea and vomiting
9. Airway complications (reported to discharge)

Overall study start date
28/09/2017

Completion date
01/01/2020

Eligibility

Key inclusion criteria
1. All cleft palate primary repairs +/- lip repairs
2. Secondary cleft palate repairs +/- lip repairs

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
50 in each arm

Total final enrolment
100

Key exclusion criteria
Current exclusion criteria as of 04/05/2021:
1. Solo cleft lip repairs

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Previous exclusion criteria:
1. Local anaesthetic allergy
2. Bleeding disorders
3. Cutaneous infection
4. Solo cleft lip repairs

Date of first enrolment
01/07/2019

Date of final enrolment
01/08/2019

Locations

Countries of recruitment
Ireland

Study participating centre
Our Lady’s Children’s Hospital Crumlin
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Sponsor information

Organisation
Our Lady's Hospital Crumlin

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Sponsor type

Hospital/treatment centre

ROR
https://ror.org/025qedy81

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Study results may be presented locally, peer review and in academic journals but no identifying data will be used.

Intention to publish date
31/12/2021

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

IPD sharing plan summary
Other