

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

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<b>Registration date</b> 18/07/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/06/2021	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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?

Dr Orla Kerr

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## Contact information

**Type(s)**

Public

**Contact name**

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**Contact details**

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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**

Cooley Road Drimnagh

Dublin

Ireland

Dublin 12

# **Sponsor information**

## **Organisation**

Our Lady's Hospital Crumlin

## **Sponsor details**

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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