# Intercostal nerve cryoablation versus thoracic epidural analgesia for minimal invasive Nuss repair of pectus excavatum: A protocol for a randomized clinical trial (ICE trial)

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Thoracic disorders (excl lung and pleura) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON53766

**Source**
ToetsingOnline

**Brief title**
ICE: Intercostal nerve Cryoablation versus Epidural analgesia

### Condition

- Thoracic disorders (excl lung and pleura)

**Synonym**
Pectus excavatum; Funnel chest

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Zuyderland Medisch Centrum
**Source(s) of monetary or material Support:** 0,Atricure

## Intervention

**Keyword:** Analgesia, Funnel Chest, Intercostal nerve cryoablation, Pectus Excavatum

## Outcome measures

### Primary outcome

Postoperative length of hospital stay will be recorded as the primary endpoint.

### Secondary outcome

Secondary outcomes include: 1) pain intensity 2) operative duration; 3) opioid usage; 4) cryoanalgesia- or epidural-related complications including neuropathic pain; 5) creatine kinase activity; 6) intensive care unit admissions; 7) readmissions; 8) mobility; 9) health related quality of Life; 10) days to return to work/school; 11) number of postoperative outpatient visits and 12) hospital costs.

# Study description

### Background summary

The minimal invasive Nuss procedure is currently considered the treatment of choice for pectus excavatum. This procedure is usually associated with severe postoperative pain as great forces are employed on the thoracic cage to correct the sternal depression. Pain is the main limiting factor for early discharge. Epidural analgesia is currently considered gold standard for postoperative pain treatment. Alternative pain management strategies (e.g., patient-controlled analgesia and paravertebral nerve block) have also been described but fail in accomplishing adequate prolonged post-operative pain management. Alternatively, continuous use of opioids comes with side-effects like severe nausea, urinary retention and obstipation. Intercostal nerve cryoablation seems a promising novel technique for postoperative analgesia. Prior studies comparing

intercostal cryoablation to other pain treatment modalities after pectus excavatum repair through the minimal invasive Nuss procedure report promising results, but pose significant limitations (e.g., small sample size, retrospective nature with non-matched patient groups or considerable confounders).

### Study objective

Primary objective of the current study is to determine the impact of intercostal nerve cryoablation on postoperative length of hospital stay compared to standard pain management of pectus excavatum patients treated with the minimal invasive Nuss procedure.

### Study design

The study protocol is designed for a single center, prospective, unblinded randomized clinical trial comparing intercostal nerve cryoablation with thoracic epidural analgesia in pectus excavatum patients treated with the minimal invasive Nuss procedure. Block randomization, including stratification based on age and gender, with an allocation ratio of 1:1 will be performed.

### Intervention

Intercostal nerve cryoablation complemented with intercostal nerve blocks.

### Study burden and risks

The risks for study participants are negligible as the cryoablation technique has already been effectively used in the Nuss procedure without any serious side effects (17-25). In case of neuropathic pain, the patient will be referred to the pain specialist. Also, participants will be monitored daily by nursing staff and surgeons while admitted to the hospital. Video recordings of the surgical procedure made with the videoscope will be stored in the electronic patient file of each patient. Possible side effects related to the intervention will be fully investigated and reported for the entire study period.
Burden associated with participation in this study consists of the completion of three questionnaires on 4 different timepoints. This will take 10 minutes per timepoint. Furthermore, one extra venous blood sampling will be performed.
Possible benefit consists of more successful pain management and therefore shorter length of postoperative hospital stay and better recovery.

## Contacts

### Public

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

## Inclusion criteria

Pectus excavatum patients, 12-24 years, who undergo the Nuss procedure

## Exclusion criteria

1. A chest wall deformity other than pectus excavatum;
2. Opioid use in the 3 months prior to surgery;
3. Pain syndrome (e.g., fibromyalgia) or neuropathic pain prior to surgical repair of Pectus Excavatum;
4. Connective tissue disease (e.g., Marfan syndrome, Ehlers-Danlos syndrome);
5. Previous thoracic surgery or pectus excavatum repair;
6. Contraindication for INC or TEA (e.g., patient refusal, infection at the site of cannulation, uncontrolled systemic infection, bleeding diathesis, increased intracranial pressure, mechanical spine obstruction);
7. Psychiatric disease currently receiving treatment;

8. Not mastering the Dutch language;
9. Participation in another clinical trial that may interfere with the current trial

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 08-12-2023 |
| Enrollment: | 50 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 04-04-2023 |
| Application type: | First submission |
| Review commission: | METC Z: Zuyderland-Zuyd (Heerlen) |
| Approved WMO Date: | 16-10-2023 |
| Application type: | Amendment |
| Review commission: | METC Z: Zuyderland-Zuyd (Heerlen) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| ClinicalTrials.gov | NCT:notyetassigned |
| CCMO | NL82316.096.23 |