ISRCTN11359779 https://doi.org/10.1186/ISRCTN11359779

A trial of surgery versus no surgery in patients with severe pectus excavatum: looking at improvements in heart and lung function

Submission date
26/04/2024

Recruitment status
Recruiting

Registration date
30/04/2024

Overall study status
Ongoing

Last Edited
26/11/2025

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Pectus Excavatum (PE), also known as funnel chest, is a condition where the ribs and breastbone grow inwards forming a dent in the chest. It can be found in between 1 in 400 and 1 in 1000 people. People with severe PE, where the space between the spine and the chest is limited, can experience symptoms such as breathlessness, dizziness, fainting and pain with exercising. This can be very restrictive in daily life.

Treatment for PE includes surgery, which lifts the sternum up, relieving these symptoms. There are no new or “experimental” procedures being tested in this study: the two types of surgeries called the Nuss and Ravitch procedures are both well-established and regularly performed in patients across the world.

In 2019 the NHS England decommissioned pectus surgery, although it is still fully-funded in the devolved nations. This decision was based on the lack of high-quality comparative data showing an improvement in physical health or heart-lung function. More recently in 2023, NHS England have started funding surgery for only the most severe cases, as assessed by a national expert Multi-Disciplinary Team (MDT), which are then performed at two hospitals in England.

The purpose of this study is to see how surgery to treat PE affects a participant’s ability to be physically active. We will recruit 300 participants overall and compare the risks and benefits of surgery against no surgery as measured by a change in physical health after a year. We will also look at how much it costs the NHS overall.

Who can participate?
Patients with pectus excavatum aged 12 years or older.

What does the study involve?
Participants will have a series of data collected when they join the trial, most data should be available from their medical records, additionally, they will need to complete a number of questionnaires. If they have consented to the trial, then they will be allocated randomly (by a

computer) to either the early or the delayed surgery arms. If they are part of the observational study, they will have the surgery as already planned.

Participants will then be followed initially for up to approximately 3 years post-surgery (at 6 months, 1 year and 3 years after surgery, and for the delayed-surgery group also at 6 months and 1 year after their allocation) and, if further funding is available, then for up to 5 years after surgery. At these follow-ups, participants will be asked about their current status, medications, any hospitalisations, adverse events and other procedures they might have undergone since their last contact point, additionally they will be asked to complete the same questionnaires as at baseline. Participants will also be asked to undergo exercise tests to measure their heart-lung function at 1 and 3 years after surgery, and for the delayed-surgery group also at 1 year after their allocation and before their surgery.

There are two types of surgery, one called Nuss and one called Ravitch. Both types are included in this study, and the surgeon will discuss them with the participant to help decide the best option. Both surgical procedures are well-established practices for the treatment of PE. As such, there are routine care practices to be followed.

What are the possible benefits and risks of participating?
The main benefit for participants in England in groups 1 and 2 is that being part of the study enables access to surgery that may not be available to them as part of NHS care; and it is expected that the surgery will improve their condition. However, there are risks associated with the surgery, including prolonged pain, infection, and complications of the procedure. In the routine surgical follow-ups, there is also the need for a CT scan, which involves a low dose of radiation; with any radiation exposure there is the risk that it may cause cancer many years later. Additional risks and burdens as research participants include the potential loss of confidentiality, as we will collect a lot of personal data, although we will recorded most of this against a code. Some people will also feel uncomfortable when answering questions about their health or healthcare.

Where is the study run from?
South Tees Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2024 to May 2030

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
RESTORE trial team, Dr Lisa Chang
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Contact information

Type(s)
Public

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
331910

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 57603, NIHR158749, IRAS 331910

Study information

Scientific Title
A randomised trial of surgery versus no treatment to RESTORE cardiopulmonary function in severe pectus excavatum

Acronym
RESTORE

Study objectives
Surgery improves physical functioning in patients with pectus excavatum, as measured at one-year.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/06/2024, East of Scotland Research Ethics Service (Tayside Medical Science Centre, George Pirie Way, Ninewells Hospital, Dundee, DD1 9SY, United Kingdom; +44 1382 383871; tay.eosres@nhs.scot), ref: 24/ES/0034

Study design
Interventional randomized controlled trial with observational cohort

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cardiothoracic surgery, pectus excavatum

Interventions
If a potential participant consents to the randomised trial, a series of screening and baseline assessments will be conducted and recorded. These include capturing data from routine care on medical history, physical exercise and lung function tests, existing scans and images that have been performed to diagnose their condition and the severity of it. In addition to capturing this routine data, participants will be asked to complete a series of questionnaires. Where the patients have had an exercise test some time ago (more than 12 months' ago for people 16 years and over, and more than 6 months' ago for people under 16 years) we will ask them to do a repeat test, as their condition might have changed.

If meeting the eligibility criteria, participants will be allocated (randomised) into one of two groups: to have early surgery (within 3 months of randomisation), or to have surgery after a 12-month delay.

For the late-surgery group, they will be contacted at 6 and 12 months after randomisation to ask about their health and complete the same questionnaires they had at baseline. At 12-months they will also be asked to repeat the exercise test.

For all groups, after surgery, as part of their routine care, it is recommended in routine care that a low-dose CT scan is performed to measure the impact of the surgery, this takes place in a timeframe of up to 6 months after surgery and we will collect this data if it is available. At 6 and

12 months after surgery, all participants will be contacted to ask about their health and complete the same questionnaires as at baseline. At 12-months after surgery they will also be asked to repeat the exercise test.

If patients undergo the Nuss surgical procedure (which involves the insertion of bars into their chest), then at any time from 2.5 - 3 years after surgery they will have the bars removed. These participants will be contacted approximately 6 months after the bars are removed to ask about their health and complete the same questionnaires. They will also be asked to repeat the exercise test.

If patients undergo the Ravitch surgical procedure, they will be contacted 3 years after surgery to ask about their health, complete the same questionnaires and to repeat the exercise test.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Current primary outcome(s) as of 26/11/2025:

1. Change in SF-36v2 Physical Function score between baseline and 1-year, using a 4-week recall period.

Primary economic outcome
1. Cost effectiveness measured in terms of incremental cost per quality-adjusted life year (QALY) gained over 1-year following index surgery

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Previous primary outcome(s):

1. SF-36v2 Physical Function score change between testing before randomisation and 1 year later (control group) or 1 year after surgery (experimental group).
2. Incremental cost per QALY at 1 year. QALY assessed through quality of life questionnaires (EQ-5D-5L, SF-36v2, HADS) completed at baseline and 1 year.

Key secondary outcome(s))
Current key secondary outcome(s) as of 26/11/2025:

1. Change in cardiopulmonary function between baseline and 1-year, assessed by percentage predicted VO_2peak on CPET.

Other secondary outcomes:
2. Measures of cardiopulmonary function by CPET and spirometry at 1-year and 3-years.
3. Quality of life measures, including those assessing mental well-being (EQ-5D-5L and SF-36v2 mental component scores) at 1-year and 3-years.
4. Anxiety and depression scores measured by HADS at 1-year and 3-years.
5. Symptoms measured by modified PEEQ and PCAPES questionnaires at 1-year and 3-years.
6. Body image measured by BIDQ at 1-year and 3-years.
7. Measures of technical operative success by Haller Index and Correction Index post-operatively.
8. Need for revision surgery (complications including unplanned redo surgery and syncope) to 1-year and 3-years.
9. Adverse events of special interest (related to PE, not the intervention) to 1-year and 3-years.

10. Major surgical complications to 1-year and 3-years.
11. Cost per participant, including intervention costs, healthcare and social care service costs, and out-of-pocket expenses for participants and their families/carers at 1-year post-intervention and over the participant's lifetime.
12. Average QALYs per participant estimated from EQ-5D-5L and SF-6D (derived from SF-36v2) over 1-year.
13. Modelled costs and QALYs over the participant's lifetime.
14. Modelled incremental cost per QALY gained over the participant's lifetime.
15. Incremental net benefit of the intervention.
16. Participants' willingness to pay for each intervention.

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Previous key secondary outcome(s):

1. Measures of cardiopulmonary function from cardiopulmonary exercise tests (CPET), at baseline, 1 year (post-surgery for all groups and also post-randomisation for the late surgery group), 3 years post-surgery.
2. Quality of life measures including those that of impact on mental well-being (EQ-5D-5L and SF36v2 mental component scores, and HADS), at baseline, 6 months, 1 year (post-surgery for all groups and also post-randomisation for the late surgery group), 3 years post-surgery.
3. Symptoms measured by Nuss and Phoenix Comprehensive Assessment of Pectus Excavatum Symptoms (PCAPES) Questionnaires, at baseline, 6 months, 1 year (post-surgery for all groups and also post-randomisation for the late surgery group), 3 years post-surgery.
4. Body image measured by the Body Image Disturbance Questionnaire (BIDQ), at baseline, 6 months, 1 year (post-surgery for all groups and also post-randomisation for the late surgery group), 3 years post-surgery.
5. Need for revision surgery (complications including the need for unplanned redo surgery and syncope), data collected across the duration of the patient's participation in the study (up to 3 years).
6. Adverse events of special interest, data collected across the duration of the patient's participation in the study (up to 3 years).
7. Major surgical complications, data collected across the duration of the patient's participation in the study (up to 3 years).
8. Costs to the NHS and patients at 1 year and over the patients' lifetime, measured by Health Resource Usage Questionnaire.
9. QALYs at 1 year and over the patients' lifetime, measured by quality of life questionnaires (EQ-5D-5L, SF-36v2, HADS).
10. Incremental cost per QALY gained over the patients' lifetime, measured by quality of life questionnaires and healthcare resource utilisation.
11. Patient preference measured by a discrete choice experiment, to be conducted at month 16 post-randomisation.
12. Net benefit of the intervention, measured by a combination of outcome measures listed above.

Completion date
31/05/2030

Eligibility

Key inclusion criteria

Current key inclusion criteria as of 09/09/2025:
For inclusion in the randomised trial:
1. ≥ 12 years old.
2. A PE deformity with a Haller Index of >3.25, as measured by the internal width of the chest measured at the widest point divided by the distance from the back of the sternum to the anterior vertebral body at its minimum point on CT scan.
3. SF36V2 physical functioning score ≤ 80
4. The participant must satisfy at least one of the following criteria:
4.1. Significant level of shortness of breath or exercise ability perceived to be below that of their peers (e.g., limited by vigorous activities such as running or lifting heavy objects).
4.2. Presyncope or syncope on exercise.
4.3. Arrhythmias on ECG that may be due to the pectus abnormality.
4.4. Dysphagia or swallowing abnormalities in the absence of any other cause.
5. Provide informed consent/assent and agree to 5 years of follow up.
6. Fit to undergo surgery.

For inclusion in the observational cohort:
1. >=12 years old.
2. Confirmed as eligible and fit for surgery via the national MDT surgical pathway.
3. Providing informed consent to take part in the embedded observational cohort
4. SF36V2 physical functioning score ≤ 80

Previous inclusion criteria:
For inclusion in the randomised trial:
1. ≥ 12 years old.
2. A PE deformity with a Haller Index of >3.25, as measured by the internal width of the chest measured at the widest point divided by the distance from the back of the sternum to the anterior vertebral body at its minimum point on CT scan.
3. The participant must satisfy at least one of the following criteria:
3.1. Significant level of shortness of breath or exercise ability perceived to be below that of their peers (e.g., limited by vigorous activities such as running or lifting heavy objects).
3.2. Presyncope or syncope on exercise.
3.3. Arrhythmias on ECG that may be due to the pectus abnormality.
3.4. Dysphagia or swallowing abnormalities in the absence of any other cause.
4. Provide informed consent/assent and agree to 5 years of follow up.
5. Fit to undergo surgery.

For inclusion in the observational cohort:
1. >=12 years old.
2. Confirmed as eligible and fit for surgery via the national MDT surgical pathway.
3. Providing informed consent to take part in the embedded observational cohort and agreeing to 5 years follow up.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
12 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 09/09/2025:
For the randomised trial:
1. Patients not fulfilling the inclusion criteria.
2. Symptoms relating to causes other than PE.
3. Unwilling to have surgery for PE.

For the observational cohort:
1. Patients not fulfilling the inclusion criteria.
2. Patients who are willing to join the full randomised trial group of the RESTORE Trial.
3. Received previous corrective surgery for PE (Nuss/Ravitch).

Previous key exclusion criteria:
For the randomised trial:
1. Patients not fulfilling the inclusion criteria.
2. Symptoms relating to causes other than PE.
3. Unwilling to have surgery for PE.

For the observational cohort:
1. Patients not fulfilling the inclusion criteria.
2. Patients who are willing to join the full randomised trial group of the RESTORE Trial.

Date of first enrolment
01/08/2024

Date of final enrolment
31/08/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

South Tees Hospitals NHS Foundation Trust
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Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request
Academic Cardiovascular Unit, South Tees Hospitals NHS Foundation Trust stees.
pectusrestoretrial@nhs.net
Aggregated coded datasets will be available to be shared upon request, following publication of the main findings. The data will be available, as described in the participant information sheet, and according to the consent provided by the participant. Requesters must provide an outline of their analysis plans and agree to adhere to UK data privacy laws as a minimum, access will be granted after consideration of the plan by the study chief investigator, trials unit and sponsor.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes