

Project scope: Vacuum bell device for the correction of pectus excavatum

October 2024

Research questions

The main research question is:

- What is the clinical effectiveness, cost effectiveness, safety and patient experience of the vacuum bell device for treatment of people with a pectus excavatum (funnel chest)?

The following supplementary questions will also be considered:

- Does the evidence for the effectiveness of the vacuum bell device differ depending on the severity of the pectus excavatum?
- What is the evidence on optimal daily wear time, and the optimal length of overall treatment duration?
- What is the evidence around patient adherence to recommended wear-time and treatment duration?
- What is the impact on the quality of life for children and young people with pectus excavatum?
- What is the optimal age to be treated with a vacuum bell device?

Inclusion criteria

The selection of studies for inclusion in the literature review element of the project will be based on the following criteria:

Population	Children and young people (aged <18 years) with pectus excavatum (of all severities)
Intervention	Vacuum bell therapy
Comparator	Minimally invasive surgery (Nuss procedure), physiotherapy and advice, no intervention
Outcomes	Sternum depth/elevation, Haller Index, cosmetic appearance, cardiorespiratory function, psychological outcomes (including body image, confidence, self esteem), cost effectiveness, safety

Planned activities

SHTG have agreed on the following activities to support the development of SHTG Recommendation on the use of the vacuum bell device for the treatment of pectus excavatum:

- A comprehensive review of published clinical-effectiveness and cost effectiveness evidence
- A review of the literature relating to patient issues associated with pectus excavatum and treatment with the vacuum bell
- A cost comparison of the clinical pathway with vacuum bell therapy for children and young people (aged <18 years) with pectus excavatum compared with current practice in two subgroups. Specifically, those currently managed conservatively/physiotherapy and advice or surgically.

Engagement

- A peer-review process will be conducted to give topic experts an opportunity to comment on the review of the evidence and the modelling work.
- A consultation exercise will be conducted to give topic experts an opportunity to comment on a draft recommendation.
- Engagement with relevant patient organisations with a view to identifying issues not highlighted in the literature

End products

At the end of the project, SHTG will publish:

- An SHTG Recommendation on the use of the Vacuum Bell device for the treatment of people with pectus excavatum, including a review of the evidence on clinical effectiveness, cost effectiveness, safety, patient issues and organisational issues.
- A plain language summary

Timescales (approximate)

February 2025