ISRCTN15355937 https://doi.org/10.1186/ISRCTN15355937

Invisible funnel chest

Submission date	Recruitment status	[_] Prospectively registered
03/06/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/06/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/07/2023	Circulatory System	

Plain English summary of protocol

Background and study aims
Pectus excavatum (PE) is a defect of the chest cartilage that causes a hollow in the sternum and thus tightness in the chest. Patients with PE are less able to exercise and often have abnormalities of the heart. There are patients who complain of cardiac symptoms without visible evidence of PE, but who have anatomical conditions on cardiac magnetic resonance (CMR) imaging, suggesting PE with an elevated Haller-Index, which measures chest cavity size.

Who can participate?
Adult patients undergoing CMR for further evaluation of the heart due to cardiac symptoms (such as palpitations, dyspnea, atypical chest pain, syncope)

What does the study involve?
Biventricular global strain analysis is assessed using feature tracking (CMR-FT). ECG and in some cases Holter recordings are performed to detect rhythm events. Cardiac symptoms are evaluated in detail using a questionnaire.

What are the possible benefits and risks of participating?
Participation in the study is not associated with any risk. In the study, MRI data collected as part of routine clinical practice will be correlated with clinical data collected using questionnaires. Further interventions are not planned. Study participation can be withdrawn at any time without giving reasons. Furthermore, there are no costs for the patients. Participation is of course voluntary. No direct benefit is expected for the individual, however, patients receive an additional free study-related visit.

Where is the study run from?
University Medical Centre Mannheim (Germany)

When is the study starting and how long is it expected to run for?
October 2019 to February 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Anna Hohneck
annalena.hohneck@umm.de

Contact information

Type(s)
Scientific

Contact name
Dr Anna Hohneck

ORCID ID
https://orcid.org/0000-0002-7629-2770

Contact details
University Medical Centre Mannheim
Medical Faculty Mannheim of Heidelberg University
Theodor-Kutzer-Ufer 1-3
Mannheim
Germany
68167
+49 (0)621 383 789 2510
annalena.hohneck@umm.de

Additional identifiers

Study information

Scientific Title
Thoracic constriction without evidence of the typical funnel-shaped depression – the invisible pectus excavatum

Study objectives
Pectus excavatum (PE) is a congenital deformity that leads to a funnel-shaped depression of the anterior chest wall. This pathognomonic feature gives the disease its common name, funnel chest. For a long time, it was assumed that PE was an inconsequential condition with symptoms rather than of a cosmetic character. However, the deformity can lead to reduced physical performance, especially during exercise, mainly caused by compression of the right ventricle. In several studies, reduced lung volumes associated with lower airway obstruction could also be observed. While the PE diagnosis can typically be made at a glance, there are patients who show only discrete indications to no visible external changes and unobtrusive echocardiography but present with non-specific cardiac symptoms. In cardiac magnetic resonance imaging (CMR), however, there is evidence of PE, with an increased Haller index, which measures chest cavity size, but without the typical funnel-shaped sternal depression. The current study investigated a case series of patients with cardiac symptoms who have received a CMR for work-up, showing thoracic constriction in terms of an invisible pectus excavatum.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 14/01/2020, Medical Ethics Commission II, Faculty of Medicine Mannheim, University of Heidelberg (House 42 - Level 3, Theodor-Kutzer-Ufer 1-3, 68167, Mannheim, Germany; +49 621 /383-71775; ethikkommission-II@medma.uni-heidelberg.de), ref: 2020-800R

Primary study design
Observational

Study design
Monocentric observational trial

Study type(s)
Screening

Health condition(s) or problem(s) studied
Patients with cardiac symptoms and elevated Haller-Index in cardiac magnetic resonance imaging

Interventions
Biventricular global strain analysis is assessed using cardiac magnetic resonance feature tracking (CMR-FT). ECG and in some cases Holter recordings are performed to detect rhythm events. Cardiac symptoms are evaluated in detail using a questionnaire.

Intervention Type
Other

Primary outcome(s)
Determination of the Haller index, defined as the ratio of the transverse thoracic diameter divided by the frontodorsal diameter of the chest, by analyzing magnetic resonance imaging (MRI) data, measured at the time of study inclusion. For this, only two distances are measured on the MRI image and related to each other.

Key secondary outcome(s)
1. Correction index, measured by cardiac magnetic resonance imaging (CMR) at the time of study inclusion. The correction index is defined as the minimum distance between the posterior sternum and anterior spine and the maximum distance between the anterior spine and most anterior portion of the chest. The difference between the two is divided by the latter (×100) to give the percentage of chest depth the defect represents.
2. Depression index, measured by CMR at the time of study inclusion. The depression index is derived from the absolute measurement of sternal depression using the transverse vertebral body diameter as a surrogate for height.
3. Intracardiac angles, measured by CMR at the time of study inclusion. Intracardiac angles were determined to describe the deviation of the heart axis by measuring three different intracardiac angles, including the angle between the perpendicular of the thorax and the apex of the right ventricular/insertion of the two ventricles/apex of the left ventricle.

Completion date
01/02/2022

Eligibility

Key inclusion criteria
Patients who undergo cardiac magnetic resonance imaging for further evaluation of the heart due to cardiac symptoms (such as palpitations, dyspnea, atypical chest pain, syncope) and unobtrusive echocardiography, with relative thoracic constriction due to an elevated Haller-Index.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
88

Key exclusion criteria
1. Inability to give informed consent
2. Definitive cardiac diagnosis

Date of first enrolment
01/02/2020

Date of final enrolment
01/02/2021

Locations

Countries of recruitment
Germany

Study participating centre
University Medical Centre Mannheim
Medical Faculty Mannheim
Heidelberg University
Theodor-Kutzer-Ufer 1-3
Mannheim
Germany
68167

Sponsor information

Organisation
University Medical Centre Mannheim

ROR
https://ror.org/05sxbyd35

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the Principal Investigator of the study Dr Anna Hohneck, annalena.hohneck@umm.de. These data are available in anonymized form so that no conclusions can be drawn about patient data. A general transfer of data to third parties is not intended. The data are archived by us for a period of 10 years and are available within this period for further analyses (e.g. as part of a meta-analysis or similar).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/07/2023	26/07/2023	Yes	No