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Predicting outcomes following intervention for tricuspid regurgitation

Submission date
10/02/2025

Recruitment status
Recruiting

Registration date
03/04/2025

Overall study status
Ongoing

Last Edited
20/05/2025

Condition category
Circulatory System

[ ] 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
This study focuses on a heart condition called tricuspid valve regurgitation (TR), where blood flows backward across the heart's tricuspid valve. This is a common issue, especially in patients who are at high risk for surgery and have had no treatment options until now. Severe TR is linked to higher death rates. Recently, new keyhole treatments have been developed that can fix the heart valve without surgery. These treatments include tricuspid transcatheter edge-to-edge repair (T-TEER) and tricuspid valve replacement (TTVR), collectively known as transcatheter tricuspid valve intervention (TTVI). The study aims to understand how patients respond to these treatments and to identify which patients might benefit the most.

Who can participate?
Patients with severe or greater tricuspid regurgitation who are considered suitable for transcatheter tricuspid valve intervention after a discussion with a multidisciplinary team can participate in this study.

What does the study involve?
Participants will undergo transcatheter tricuspid valve interventions for severe tricuspid regurgitation. They will have additional functional and quality-of-life assessments at the start of the study and during follow-up visits. The study will also involve invasive physiology assessments before and after treatment to understand how the treatment affects heart function. Researchers will look at the relationship between changes in heart function and changes in quality of life and physical ability.

What are the possible benefits and risks of participating?
The possible benefits include receiving a new treatment that could improve heart function and quality of life. However, there are risks, such as the potential for the heart to worsen suddenly if the leak is completely fixed, causing pressure overload. The study aims to identify markers that predict how well patients will respond to treatment.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
December 2024 to March 2028.

Who is funding the study?
Edwards Lifesciences (USA)

Who is the main contact?
Dr Benedict McDonaugh, benedict.mcdonaugh@gstt.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
340256

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 61262

Study information

Scientific Title
Predicting functional and clinical outcomes following transcatheter tricuspid valve intervention for severe tricuspid regurgitation

Acronym

PREDICT-TR

Study objectives
1. Baseline invasively measured contractility and ventricle-arterial coupling will predict functional response to Transcatheter Tricuspid valve intervention.
2. Atrial secondary tricuspid regurgitation (A-STR) will show an improvement in cardiac output over Ventricular secondary (V-STR) post-TTVI.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 16/12/2024, West London Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8098; westlondon.rec@hra.nhs.uk), ref: Reference number not provided

Study design
Multicentre observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Quality of life, Treatment, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Tricuspid regurgitation, heart failure

Interventions
We will observe patients undergoing Transcatheter Tricuspid valve interventions for severe tricuspid regurgitation. We will perform some additional functional and quality-of-life assessment at baseline and at follow-up to try and understand which patients yield the greatest benefit from treatment. We will perform invasive physiology assessment before and after treatment to understand how the treatment affects cardiovascular physiology. We will assess the correlation between changes in invasive physiology and changes in quality-of-life and functional capacity. The overall aim of the study is to assess which baseline clinical, imaging and physiology characteristics correlate with treatment response to refine patient selection for tricuspid interventions.

Intervention Type
Other

Primary outcome measure
1. Cardiac output measured invasively immediately before and after tricuspid intervention procedure.
2. Cardiac output measured non-invasively at baseline, the day of and <48hrs after tricuspid intervention procedure, at 12 weeks follow-up

Secondary outcome measures
1. Change in cardiac contractility measured invasively: measured immediately before and after tricuspid intervention procedure.
2. Change in cardiac function (ejection fraction and cardiac output) measured with non-invasive cardiac imaging: measured at baseline, the day of and <48hrs after tricuspid intervention procedure, at 12 weeks follow-up
3. Change in symptoms measured with the Kansas City Cardiomyopathy Questionnaire (KCCQ): measured at baseline and at 12 weeks follow-up
4. Change in exercise capacity measured with 6-minute walk test (6MWT) and average daily step count measured with wearable activity monitors: measured at baseline and at 12 weeks follow-up

Overall study start date
16/12/2024

Completion date
01/03/2028

Eligibility

Key inclusion criteria
Patients with severe or greater tricuspid regurgitation and deemed suitable for Transcatheter tricuspid valve intervention after multidisciplinary team discussion.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
72

Key exclusion criteria
1. Anatomical or haemodynamic exclusion for TTVI
2. Pregnancy
3. Age <18 years

4. Congenital heart disease requiring intervention/surgery
5. Significant (>moderate in severity) non-tricuspid valvular disease
6. Another indication for cardiac surgery
7. Enrolment in other studies that may lead to deviation from either protocol

Date of first enrolment
01/03/2025

Date of final enrolment
01/03/2028

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's and St Thomas' Hospitals
Trust Offices
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
Royal Brompton Hospital
Sydney Street
London
United Kingdom
SW3 6NP

Study participating centre
John Radcliffe Hospital
Headley Way
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Industry

Funder Name
Edwards Lifesciences

Alternative Name(s)
Edwards, Edwards Lifesciences Corporation, Edwards Lifesciences Corp., Edwards Lifesciences LLC, ELC

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Data will be published in peer-reviewed journals and via conference presentations. Lay summary of results will be made available via study website.

Intention to publish date
01/03/2029

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon written request from the research team - contactable via Dr Tiffany Patterson, Consultant Cardiologist, St Thomas' Hospital, Westminster Bridge Road, London, SE1 9RT.

IPD sharing plan summary
Available on request