

# Successful 'first in human' clinical trial of pioneering guidance for heart bypass surgery

April 8 2024

---



Professor Patrick W Serruys and Professor Yoshi Onuma in the CORRIB Core Lab at University of Galway. Credit: University of Galway

A new approach to the guidance, planning and conduct of heart bypass surgery has been successfully tested on patients for the first time in a

clinical trial coordinated by a research team at University of Galway.

The FAST TRACK CABG study, overseen by the University's CORRIB Research Center for Advanced Imaging and Core Lab, has seen heart surgeons plan and carry out [coronary artery bypass](#) grafting (CABG), based solely on non-invasive cardiac-CT scan images, with HeartFlow's AI-powered blood flow analysis of the patient's coronary arteries.

The [research](#) was published in the *European Heart Journal*.

The key findings of this first-in-human study is the 99.1% feasibility, which means that heart bypass surgery without undergoing invasive diagnostic catheterization is feasible and safe, driven by the good diagnostic accuracy of the cardiac CT scan and AI-powered blood flow analysis.

In comparing the safety and effectiveness of heart bypass surgery, the trial had similar outcomes to recent surgical groups of patients who underwent conventional invasive angiogram investigations, which involves inserting a catheter through an artery in the wrist or groin to access diseased arteries and using dye to visualize blockages.

The findings of the FAST TRACK CABG trial suggest that the less invasive approach to heart bypass surgery offers comparable safety and efficacy to established methods. The research team noted that safety issues inherent to invasive investigation can be replaced by a non-invasive technique using CT scan imaging and AI-powered blood flow analysis.

Trial chairman Professor Patrick W Serruys, Established Professor of Interventional Medicine and Innovation at University of Galway, said, "The results of this trial have the potential to simplify the planning for patients undergoing [heart bypass surgery](#). The trial and the central role

played by the CORRIB Core Lab puts University of Galway on the frontline of cardiovascular diagnosis, planning and treatment of coronary artery disease."

The study was carried out in leading cardiac care hospitals in Europe and the US and involved 114 patients who had severe blockages in multiple vessels, limiting blood flow to their heart.

The cardiac CT used in this study (Revolution CT, GE Health care) has a special resolution that makes the non-invasive images as good or even better than the images traditionally obtained by a direct injection of contrast dye in the artery of the heart through a catheter.

During the trial, the analysis of high resolution cardiovascular imagery and data was carried out by the CORRIB Core Lab team and shared by telemedicine with surgeons in trial hospitals.

The HeartFlow Analysis, which provides AI-powered blood flow analysis called Fractional Flow Reserve derived from CT (FFRCT), quantifies how poorly the narrowed vessel provides blood to the heart muscle, assisted the surgeon in clearly identifying which of the patient's vessels should receive a bypass graft.

Professor Serruys added, "The potential for surgeons to address even the most intricate cases of coronary artery disease using only a non-invasive CT scan, and FFRCT represents a monumental shift in health care. Following the example of the surgeon, [interventional cardiologists](#) could similarly consider circumventing traditional invasive cineangiography and instead rely solely on CT scans for procedural planning. This approach not only alleviates the diagnostic burden in cath labs but also paves the way for transforming them into dedicated 'interventional suites'- ultimately enhancing patient workflows."

Dr. Yoshi Onuma, Professor of Interventional Cardiology at University of Galway and the medical director of CORRIB Research Center, said, "Exploring the potential for minimizing diagnostic catheterization procedures is important for several reasons- a catheterization procedure is invasive and it is unpleasant for the patient. It is also costly for the health service. While there is a minimal risk associated with the procedure, it is not entirely risk free.

"CT scan analysis, FFRCT, and guidance from the team in Galway is a world first in bypass surgery. It may become a game-changer, altering the traditional relationship between GP, radiologist, cardiologist and cardio-thoracic surgeon for the benefit of the patient."

Dr. Saima Mushtaq, Director of Cardiovascular CT in Centro Cardiologico Monzino, Milan, Italy, said, "This is a historical trial that may change our approach for patients who are candidates for CABG revascularization and with the FAST TRACK CABG trial we have been part of this revolution in which a CT scan is considered a tool to plan revascularization skipping invasive coronary angiography."

Dr. John Puskas, Mount Sinai Morningside, New York and Professor of Cardiothoracic Surgery, Emory University Hospital Midtown, Atlanta, Georgia, said, "As the only North American surgeon, enrolling many patients in this trial, I have a unique perspective: I can conclusively state that there is no loss in diagnostic precision or accuracy nor any decrement in the quality of surgical planning or performance when the surgical team is guided solely by data from a latest-generation, non-invasive coronary CT scan.

"Once the surgeon is familiar with this new imaging modality, there are several ways in which it is actually a better guide than the historical invasive coronary angiogram."

Professor Fidelma Dunne, Director of the Institute for Clinical Trials at University of Galway, said, "The outcomes of this inaugural human trial are highly promising, prompting further exploration of the advantages offered by this non-invasive methodology through an extensive randomized trial. At the Institute for Clinical Trials we are committed to conducting high-impact trials that have the potential to revolutionize patient care globally."

The pioneering research of the CORRIB Core Lab at University of Galway into cardiovascular diagnosis and coronary artery disease will be further investigated in a large scale randomized trial. The research team is planning for it to involve more than 2,500 patients from 80 hospitals across Europe.

**More information:** Patrick W Serruys et al, Coronary bypass surgery guided by computed tomography in a low-risk population, *European Heart Journal* (2024). [DOI: 10.1093/eurheartj/ehae199](https://doi.org/10.1093/eurheartj/ehae199)

Provided by University of Galway

Citation: Successful 'first in human' clinical trial of pioneering guidance for heart bypass surgery (2024, April 8) retrieved 21 May 2024 from <https://medicalxpress.com/news/2024-04-successful-human-clinical-trial-guidance.html>

<p>This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.</p>
--