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| **Synergy between PCI with TAXUS and Cardiac Surgery: *SYNTAX E*xtended *S*urvival (SYNTAXES)** |
| **This is a privacy notice for patients who took part in the SYNTAX Trial****Duration: Dec 2016 - Sep-2019** |

**Key contacts:**Zoe Nicholas, Karen Banks, Daniel J.F.M. Thuijs

**Chief Investigator:**Professor Nicholas Curzen

**1. Research category**

The SYNTAX trial was originally a multicentre, randomized clinical trial to compare the efficacy of percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) up to 5-year follow-up. **SYNTAXES**, the current 10-year follow-up study, is an investigator-driven, retrospective, non-interventional and multicentre study to compare the long-term survival with PCI using paclitaxel-eluting stents versus CABG. Ethical committee approval was previously provided for the SYNTAX study. The SYNTAXES study has received ethical approval and is currently registered on ClinicalTrials.gov: [NCT03417050](https://clinicaltrials.gov/ct2/show/NCT03417050?term=SYNTAXES&rank=1).

 **2. Background**Ischemic heart disease remains the number one cause of death in Western countries. PCI and CABG are excellent treatment options for patients requiring myocardial revascularization. Randomized comparisons between PCI and CABG are extremely costly and therefore limited studies have been performed to determine the best treatment. The SYNTAX trial was the first large-scale randomized trial that randomly assigned patients to CABG versus PCI with drug-eluting stents, and is currently considered to be the most important trial of CABG versus PCI.

The primary endpoint of the trial showed that PCI was not non-inferior to CABG in terms of major adverse cardiac or cerebrovascular events (MACCE) at one year. Follow-up to 5 years demonstrated that curves continued to diverge between PCI and CABG, with significantly lower rates of cardiac death, myocardial infarction and repeat revascularization in favour of CABG. Findings from subgroup analyses have been crucial in determining the most appropriate treatment strategy according to baseline factors. Outcomes differed substantially between patients with three vessel disease (3VD) or left main (LM) disease. Those with LM disease had similar outcomes with PCI and CABG, while those with 3VD had significantly better outcomes with CABG. In addition, the SYNTAX score, an angiographically based risk model, showed itself to be a useful tool to stratify which patients should undergo PCI or CABG, with CABG being the preferred strategy especially in patients with more complex lesions.

Both European and North American guidelines on PCI and CABG have been heavily influenced by the results of 5-year follow-up results from the SYNTAX trial. The SYNTAX trial was completed at 5 years follow-up. Other previous trials on PCI versus CABG have also not extended follow-up beyond 5 years, with the exception of the GABI and BARI trials. Therefore, numerous questions on the debate of CABG versus PCI remain unanswered. Subgroup analyses, which have more limited statistical power because of the smaller groups, could significantly benefit from extended follow-up. The key objective of this study is to provide long-term data on PCI with drug-eluting stents versus CABG for complex coronary artery disease, and identify key factors for decision-making between both therapies.

**3. Objectives**

Provide long-term survival-data (10 year follow-up) on PCI with drug-eluting stents versus CABG for complex three-vessel or left main coronary artery disease, and identify patient characteristics and key factors that should be discussed during Heart Team decision making between Interventional Cardiologists and Cardiac Surgeons.

**4. Data collection**

The previous SYNTAX study protocol was approved by the institutional review board of all 85 participating hospitals, and is consistent with the International Conference on Harmonisation Guidance of Industry E6 Good Clinical Practice, the Declaration of Helsinki, and all local regulations. Written informed consent was obtained from all participating subjects at enrolment, inclusive of the 5 year follow-up.

University Hospitals Southampton NHS Foundation Trust (UHS) will act as data processor, and will be sole recipient of all patient identifiable data. UHS will contact all UK sites requesting SYNTAX study patient’s and NHS numbers. When all participating sites have returned this information, UHS will request mortality data for all English sites from NHS Digital at the 10 year follow-up time point. The completed data set will then be redacted of all identifiable information, leaving only the patient SYNTAX study ID and 10 year vital status.

The data will be encrypted and safely transferred to the sponsor (e.g. Principal Investigator: Dr Stuart J. Head and Daniel J.F.M. Thuijs, Erasmus MC, Rotterdam, The Netherlands).

**5. Data base information**

A pseudo anonymised database of patients enrolled in the SYNTAX trial is already available with baseline characteristics, procedural characteristics, and outcome data, which has been used for multiple publications. All patients included in the database have been assigned a unique study number. Patient identifiable data relating to the unique study ID is only available at individual sites. Local investigators from the English sites will send NHS patient data identifiable by unique study number and NHS number to the Principal Investigator’s site in Southampton (UHS). UHS will request from NHS Digital the survival data of each individual SYNTAXES patients.

A central database of all 1800 SYNTAXES patients will be stored at the Department of Cardiothoracic Surgery in Rotterdam, The Netherlands. This database in comparison to the already existing database will be edited only by changing the duration of follow-up, date of death if this occurred, and the cause of death where available. The remainder of the database will not be changed.

**6. Secure storage and processing of patient information**

This study has already received research ethics approval – a process designed to make sure researchers can benefit from accessing data while minimizing risk of any harm to patients - and Health Research Authority Confidential Advisory Group Section 2.51 approvals. The legal basis for processing the data is covered under General Data Protection Regulations (GDPR), Article 6 (1) (e) and Article 9 (2) (j).

Personal data of patients (NHS number, date of birth, sex, and unique study ID) will be securely transferred between individual Trusts and University Hospital Southampton NHS FT and then forwarded by Southampton, who process the survival data, to NHS Digital, who control the Civil Registration Mortality (survival) data. This is considered to be personal data according to European data protection rules, GDPR. As Southampton and NHS Digital hold the data, and are involved in processing, they are called data processors. The sponsor of the study, the Erasmus University Medical Centre, is called the data controller. The purpose of sending this personal data between the UHS organization and NHS Digital is so NHS Digital can link these data together for the same patients, to provide more accurate and complete information for researchers who can track a patient’s journey through the NHS system. However, the Sponsor will not have access to any personal identifiable data, and will not be able to identify patients using the information that they are given by University Hospital Southampton NHS FT

NHS Digital will securely transfer pseudo anonymised data to researchers at University Hospital Southampton NHS FT. Pseudo anonymised means that most identifying fields within a database are replaced with artificial identifiers, or pseudonyms so patient information can be processed without researchers being able to identify patients. Finally, all pseudo anonymised data will be securely transferred from University Hospital Southampton NHS FT to the Cardiothoracic Surgery department of the Erasmus Universtity Medical Centre, in The Netherlands. All patient information will be stored on a secure network that is password-protected, and can only be accessed by those with specialised training and access for the duration of the study.

The data will be stored by researchers at Cardiothoracic Surgery department of the Erasmus Universtity Medical Centre until 2020 for analysis and dissemination purposes. All data will be published anonymously in peer-reviewed medical journals and/or at (inter)national medical conferences. After that the data is stored, by law and regulations of the Dutch Healthcare system, until 2035, after which the data will be securely destroyed.

**University Hospital Southampton NHS FT Data Protection:**

University Hospital Southampton NHS FT is required by law to comply with data protection legislation. The UK’s regulator for the legislation is the Information Commissioner’s Office. It is the commitment of the hospital to ensure that every current employee and registered student complies with this Act to ensure the confidentiality of any personal data held by UHS, in whatever medium. This Act came into force on 25 May 2018.

University Hospital Southampton NHS FT processes the personal data of living individuals such as its staff, students, contractors, research subjects and customers. University Hospital Southampton NHS FT has a data protection and confidentiality policy (2018) as a commitment to the safeguarding of personal data processed by its staff and students, and to ensure compliance with the legislation. It is the duty of data controllers, such as University Hospital Southampton NHS FT, to comply with the data protection principles with respect to personal data. This policy describes how University Hospital Southampton NHS FT will discharge its duties in order to ensure continuing compliance with the Act in general and the data protection principles and rights of data subjects in particular.

Further information may be accessed through the following University Hospital Southampton NHS FT link:

<http://www.uhs.nhs.uk/ClinicalResearchinSouthampton/Public-and-patients/Get-involved/General-Data-Protection-Regulation.aspx>

or the following link for the Erasmus University Medical Centre (in Dutch): <https://autoriteitpersoonsgegevens.nl/nl/onderwerpen/avg-nieuwe-europese-privacywetgeving/controle-over-je-data>

or the following link to the UK Information Commissioner’s Office (ICO):

<https://ico.org.uk/>

**Data Protection Officer Contact details:**

Data protection officer

Trust Headquarters

University Hospital Southampton

Tremona Road

Southampton

SO16 6YD

For additional contact details please access above UHS link

**Opting-out**

We are happy to discuss your rights to protect your data, and how exactly it will be used in our research. If you would like further information about the use of your data in this research study, or would like to lodge a complaint to a supervisory authority – please contact us on the details given below. If you would like to request that your confidential patient information is not included in this study, please contact us between 1st February- 1st July 2019.

Contact details:

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***SYNTAXES TRIAL –*** *a 10 year follow-up for patients previously enrolled in the SYNTAX TRIAL*

*The SYNTAX trial was the first large-scale randomized trial that randomly assigned patients with coronary artery disease to undergo Coronary Artery Bypass Grafting (CABG) or Percutaneous Coronary Intervention (PCI) with drug-eluting stents. Its currently considered to be the most important trial of CABG versus PCI. Follow-up of patients to 5 years was successfully completed and showed that CABG should remain the standard of care for patients with three vessel coronary artery disease. There has never been longer term follow-up information about the survival of patients comparing CABG surgery with stents for complicated coronary disease before. Therefore, we are collecting 10 year mortality data for these patients in the original SYNTAX trial. This will involve accessing information through a national database and will not involve contacting patients, family or friends.*

*If you were previously enrolled into the SYNTAX trial and would prefer not to have this information about you included in the ten year follow-up, please contact your local research team via the contact details below:*

*Name of consultant: Professor Nicholas Curzen*