Cardiovascular atherosclerosis and percutaneous transluminal interventions

Submission date	Recruitment status No longer recruiting	Prospectively registered		
23/09/2016		Protocol		
Registration date	Overall study status	Statistical analysis plan		
20/11/2016	Completed	[X] Results		
Last Edited 18/11/2016	Condition category Circulatory System	[] Individual participant data		
16/11/2010	Circulatory System			

Plain English summary of protocol

Background and study aims

Atherosclerosis is the build-up of fatty material inside the arteries (blood vessels), which leads to heart attacks and strokes. It can be treated with a procedure called percutaneous coronary intervention (PCI), where a short wire-mesh tube, called a stent, is inserted into the artery to allow the blood to flow more freely. The aim of this study is to set up a registry (database) to follow the clinical outcomes of patients who have undergone PCI for atherosclerosis in order to improve the quality of patient care.

Who can participate?

Patients over 20 years old who have undergone PCI for atherosclerosis

What does the study involve?

Clinical data is collected about patients who underwent PCI at Chang Gung Memorial Hospital since November 1995. Deaths, heart attacks, and further stenting/surgery are all measured. The patients do not undergo any additional tests or treatment for the purposes of this study.

What are the possible benefits and risks of participating?

The results of this study may improve the quality of patient care. There are no risks involved.

Where is the study run from?

Chang Gung Memorial Hospital (Taiwan)

When is the study starting and how long is it expected to run for? June 2011 to June 2021

Who is funding the study? Investigator initiated and funded

Who is the main contact? Dr I-Chang Hsieh

Contact information

Type(s)

Scientific

Contact name

Dr I-Chang Hsieh

Contact details

No. 5 Fu-Hsing Street, Kweishan Taoyuan Taiwan 333

Additional identifiers

Protocol serial number

CORPG3C0162

Study information

Scientific Title

Cardiovascular Atherosclerosis and Percutaneous TrAnsluminal INterventions (CAPTAIN)

Acronym

CAPTAIN

Study objectives

The CAPTAIN registry is a prospective, physician-initiated, single-center observational database to evaluate patients' clinical and angiographic outcome after stenting with different type stents.

Previous studies has showed thant the use of drug eluting stent (DES) is associated with better angiographical outcome then the baremetal stent (BMS) did in coronary artery lesions, however, the results in different vessels, patients, or stent designs varied. This observational registry is to evaluate the clinical and angiographic outcome of different settings.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board of Chang Gung Memorial Hospital Medical Foundation, 21/06/2011

Study design

Prospective single-center observational study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Coronary disease receiving coronary artery stents

Interventions

The coronary intervention results and prognosis of 5000 people before June 2011 were traced via medical record review and telephone follow-up. These data were all digitized. All clinical data were collected and the prognosis of all patients receiving PCI was evaluated. Data was analyzed with t-test or analysis of variance (ANOVA) with post hoc Tukey and Duncan tests via SPSS software. P value below 0.05 was meaningful statistically.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Major adverse cardiac event (MACE) such as cardiac death, myocardial infarction (STEMI or NSTEMI), target lesion revascularization (TLR), stenting in a new lesion, and the need for emergency bypass surgery during long-term follow-up after coronary stentings

Key secondary outcome(s))

Cardiovascular events during the follow-up period including total death (cardiac and non-cardiac), reinfarction (STEMI or NSTEMI), or a cerebrovascular accident (CVA) after coronary stentings

Completion date

15/06/2021

Eligibility

Key inclusion criteria

- 1. Evidence of myocardial ischemia
- 2. >50% stenosis in a native coronary artery or in a bypass vein graft that was suitable for stenting
- 3. Over 20 years old
- 4. Had received coronary intervention
- 5. Patient and family members agreed to further follow-up

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

- 1. Severe multivessel disease requiring bypass surgery
- 2. Contraindication for aspirin, ticlopidine, clopidogrel or ticagrelor use
- 3. Patients who refused to undergo the procedure
- 4. Patients who refused further follow-up

Date of first enrolment

16/06/2011

Date of final enrolment

15/06/2021

Locations

Countries of recruitment

Taiwan

Study participating centre Chang Gung Memorial Hospital

No. 5 Fu-Hsing Street Kweishan Taoyuan Taiwan 333

Sponsor information

Organisation

Chang Gung Medical Foundation

ROR

https://ror.org/02verss31

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

For the sake of confidentiality of personal data, participant level data is not expected to be available.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2013	Yes	No
Results article	results	01/11/2013	Yes	No
Results article	results	11/04/2014	Yes	No
Results article	results	25/09/2015	Yes	No
Results article	results	01/07/2017	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes