

# Cardiovascular atherosclerosis and percutaneous transluminal interventions

<b>Submission date</b> 23/09/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/11/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/11/2016	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## 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 that 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

**Primary study design**

Observational

**Study design**

Prospective single-center observational study

**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?
<a href="#">Results article</a>	results	01/05/2013		Yes	No
<a href="#">Results article</a>	results	01/11/2013		Yes	No
<a href="#">Results article</a>	results	11/04/2014		Yes	No
<a href="#">Results article</a>	results	25/09/2015		Yes	No
<a href="#">Results article</a>	results	01/07/2017		Yes	No