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Cardiovascular atherosclerosis and percutaneous transluminal interventions

Submission date
23/09/2016

Recruitment status
No longer recruiting

Registration date
20/11/2016

Overall study status
Completed

Last Edited
18/11/2016

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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

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 measure
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

Secondary outcome measures
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

Overall study start date
16/06/2011

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

Age group
Adult

Sex
Both

Target number of participants
20000

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

Sponsor details
No. 5 Fu-Hsing Street
Kweishan
Taoyuan
Taiwan
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Sponsor type
Hospital/treatment centre

Website
https://www.cgmh.org.tw/eng2002/center_main.htm

ROR
https://ror.org/02verss31

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Intention to publish date
30/06/2017

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