

The impact of anti-diabetic drugs on the outcomes of heart attacks

Submission date 12/09/2018	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 04/10/2018	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 04/10/2018	Condition category Circulatory System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims?

Diabetes mellitus (DM) is associated with increased cardiovascular morbidity and mortality. Coronary artery disease (CAD) is the most common cause of cardiovascular morbidity and mortality. There are four times as many cardiovascular deaths in diabetic patients compared to non-diabetic patients. In particular, after acute coronary syndrome or heart attacks, patients with DM have been reported to have worse survival rates compared to those without DM. Hyperglycemia (high blood sugar) is an important predictor of long-term outcomes after acute coronary events. The management of many risk factors including blood pressure and cholesterol has been shown to reduce these complications in patients with type 2 DM. Therefore, lifestyle changes and management of hyperglycemia is recommended in current clinical guidelines. To reach this goal, combining therapy with oral anti-diabetic drugs (OADs) is very common. The study aimed at investigating the relationship between anti-diabetic drugs and the outcomes of acute coronary syndrome.

Who can participate?

Diabetic patients aged 20 years or older, who are hospitalized due to acute coronary syndrome

What does the study involve?

The study will collect clinical information related to acute coronary syndrome by reviewing medical records or interviewing with the patients at regular intervals.

What are the possible benefits and risks of participating? The participation of patients will benefit in the exploration of knowledge about the impact of OADs on the outcomes of acute coronary syndrome. There are no known risks to participants taking part in this study.

Where is the study run from?

Taiwan Society of Cardiology, Taipei (Taiwan)

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

July 2013 to January 2017

Who is funding the study?
Taiwan Society of Cardiology (Taiwan)

Who is the main contact?
Prof. Kuo-Gi Hsyu
m002018@ms.skh.org.tw

Contact information

Type(s)
Scientific

Contact name
Prof Kuo-Gi Hsyu

Contact details
No. 95, Wen Chang Road, Shih Lin District,
Taipei
Taiwan
112

Additional identifiers

Protocol serial number
102-051-E

Study information

Scientific Title
A prospective observational study of cardiovascular morbidity and mortality of acute coronary syndrome in patients with type 2 diabetes receiving different oral anti-diabetic drugs (OADs)

Study objectives
The aim of the study is to evaluate the relations between anti-diabetic drugs and the outcomes after acute coronary syndrome

Ethics approval required
Old ethics approval format

Ethics approval(s)
IRB of National Taiwan University Hospital, Hsinchu Br., 01/11/2013, IRB No.102-051-E

Primary study design
Observational

Study design
Observational cohort study

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Diabetic patients with acute coronary syndrome

Interventions

After enrolment, the participants will be reviewed by medical records and interview as needed, at enrolment, discharge, and 1, 6, 12, 24 months after discharge, to collect information related to acute coronary syndrome, including mortality, myocardial infarction, hospitalisation and cardiovascular death. The total duration of follow-up was 24 months after enrolment.

Intervention Type

Drug

Phase

Not Specified

Primary outcome(s)

Cumulative one-year mortality, assessed by reviewing medical records and interviews with patients at the baseline, discharge and 1, 6, 12 and 24 months after discharge

Key secondary outcome(s)

The following will be assessed by reviewing medical records and interviews with patients at the baseline, discharge and 1, 6, 12 and 24 months after discharge:

1. In hospital outcome
2. Cumulative one-year cardiovascular events

Completion date

18/01/2017

Eligibility**Key inclusion criteria**

1. Aged 20 years or older
2. Diagnosed with acute coronary syndrome within 30 days prior to enrolment
3. Type 2 diabetes mellitus (newly or previously diagnosed)
4. Provided informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Acute coronary syndrome caused by major trauma, GI bleeding, surgery, or endovascular interventions
2. Participating in other clinical trials

Date of first enrolment

01/11/2013

Date of final enrolment

30/09/2016

Locations**Countries of recruitment**

Taiwan

Study participating centre

Taiwan; National Taiwan University Hospital

No. 7

Zhongshan South Road

Zhongzheng District

Taipei City

Taiwan

100

Study participating centre

Mac Kay Memorial Hospital

No. 92

Section 2

Zhongshan N Rd

Zhongshan District,

Taipei City

Taiwan

101

Study participating centre

Taipei Veterans General Hospital

No. 201

Section 2

Shipai Road

Beitou District

Taipei City

Taiwan

112

Study participating centre
Shin Kong Wu Ho-Su Memorial Hospital
No. 95
Wenchang Road
Shilin District
Taipei City
Taiwan
112

Study participating centre
Tri-Service General Hospital
No. 325
Section 2
Chenggong Road
Neihu District
Taipei City
Taiwan
114

Study participating centre
Wan fang Hospital
No. 111
Section 3
Xinglong Road
Wenshan District
Taipei City
Taiwan
116

Study participating centre
Cheng Hsin General Hospital
No. 45
Zhenxing Street
Beitou District
Taipei City
Taiwan
112

Study participating centre
Cathay General Hospital
No. 280

Section 4
Ren'ai Road
Da'an District
Taipei City
Taiwan
106

Study participating centre
Far Eastern Memorial Hospital
No. 21
Section 2
Nanya South Road
Banqiao District
New Taipei City
Taiwan
220

Study participating centre
Shuang Ho Hospital
No. 291
Zhongzheng Road
Zhonghe District
New Taipei City
Taiwan
235

Study participating centre
Lin kou Chang Gung Memorial Hospital
No. 5
Fuxing Street
Guishan District
Taoyuan City
Taiwan
333

Study participating centre
Taipei Tzu Chi Hospital
No. 289
Jianguo Road
Xindian District
New Taipei City
Taiwan
231

Study participating centre

Lo-Tung Poh-Ai Hospital

No. 83, Nanchang Street

Luodong Township

Yilan County

Taiwan

265

Study participating centre

Yang-Ming University Hospital

No. 152

Xinmin Road

Yilan City

Yilan County

Taiwan

260

Study participating centre

Chung-Shan Medical University Hospital

No. 110

Section 1

Jianguo North Road

South District

Taichung City

Taiwan

402

Study participating centre

China Medical University Hospital

No. 2

Yude Road

North District

Taichung City

Taiwan

404

Study participating centre

Taichung Veterans General Hospital

No. 1650

Section 4

Taiwan Boulevard
Xitun District
Taichung City
Taiwan
407

Study participating centre
Yunlin Branch, Taiwan; National Taiwan University Hospital
No. 579
Sec. 2
Yun-Lin Rd.
Douliou City
Taiwan
640

Study participating centre
Kuang Tien General Hospital
No. 117
Shatian Road
Shalu District
Taichung City
Taiwan
433

Study participating centre
National Cheng Kung University Hospital
No. 138
Shengli Road
North District
Tainan City
Taiwan
704

Study participating centre
Chi mei Medical Center
No.901
Zhonghua Rd.
Yongkang Dist.
Tainan City
Taiwan
710

Study participating centre
Chang Gung Memorial Hospital, Kaohsiung
No. 123
Dapi Road
Niaosong District
Kaohsiung City
Taiwan
833

Study participating centre
Kaohsiung Veterans General Hospital
No. 386
Dazhong 1st Road
Zuoying District
Kaohsiung City
Taiwan
813

Study participating centre
E-Da Hospital, Kaohsiung
No.1
Yida Road
Jiaosu Village
Yanchao District
Kaohsiung City
Taiwan
821

Study participating centre
Kaohsiung Medical University Hospital
No. 100
Ziyou 1st Road
Sanmin District
Kaohsiung City
Taiwan
807

Study participating centre
National Taiwan University Hospital, Hsinchu Branch
No. 25
Lane 442
Section 1

Jingguo Road
North District
Hsinchu City
Taiwan
300

Study participating centre
Ping Tung Christian Hospital
No. 60
Dalian Road
Pingtung City
Taiwan
900

Sponsor information

Organisation
Taiwan Society of Cardiology

ROR
<https://ror.org/00j2yyv15>

Funder(s)

Funder type
Not defined

Funder Name
investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other