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

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

Study design

Observational cohort study

Primary study design

Observational

Study type(s)

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

Study outputs

Output type

Details