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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?
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Contact information

Type(s)
Scientific

Contact name
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112

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Not Specified

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

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 measure
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

Secondary outcome measures
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

Overall study start date
01/07/2013

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

Age group
Adult

Sex
Both

Target number of participants
2000

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

Sponsor details
13F-1, No. 11, Min-Chuan W. Road, Taipei 10452, Taiwan, R.O.C
Taipei
Taiwan

104
886-2-2597-6177
tsoc@tsoc.org.tw

Sponsor type
Not defined

Website
http://www.tsoc.org.tw/

ROR
https://ror.org/00j2yyv15

Funder(s)

Funder type
Not defined

Funder Name
investigator initiated and funded

Results and Publications

Publication and dissemination plan
Publication in a high-impact peer-reviewed journal is planned, two years after the overall end of the trial

Intention to publish date
18/01/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other