ISRCTN13124221 https://doi.org/10.1186/ISRCTN13124221

Narrowing of the main artery by the build-up of calcium in patients with type 2 diabetes

Submission date	Recruitment status	[ ] Prospectively registered
18/04/2020	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/04/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/04/2020	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Type 2 diabetes is a common condition that causes the level of sugar (glucose) in the blood to become too high. It's caused by problems with a chemical in the body (hormone) called insulin. It's often linked to being overweight or inactive, or having a family history of type 2 diabetes. Type 2 diabetes accelerates atherosclerosis and increases cardiovascular disease (CVD) morbidity including coronary artery disease (CAD), cerebral infarction (CI), and peripheral artery disease (PAD). The clinical assessment of cardiovascular risk in individual patients with type 2 diabetes is required for proper management. However, little is known about the significance of each clinical indicator in estimating disease progression.

The aorta is the main artery of the body, supplying oxygenated blood to the circulatory system. Abdominal aortic calcification occurs when calcium crystals are deposited in the abdominal aorta. This can cause the aorta to narrow and restrict blood flow. Abdominal aortic calcification (AAC) is a known marker of systemic atherosclerosis burden. The risk of AAC is reportedly lower among Hispanic and African Americans, but not among Chinese-Americans, compared with the risk in Caucasians. These ethnic differences in the significance of AAC cannot be explained by differences in classical CVD risk factors. The prevalence of coronary calcification also reportedly differs between Caucasians and Chinese, despite similar prevalences of AAC in these two ethnic groups. Few studies have investigated the clinical significance of AAC in patients with type 2 diabetes.

In this study, the researchers investigated the association between AAC and CVD and explored factors related to AAC progression in Japanese patients with type 2 diabetes.

Who can participate?

Adults aged 20 or over with type 2 diabetes.

What does the study involve?

Participants who had undergone a standing lateral abdominal radiography examination between 2 months before and 2 months after admission were eligible for inclusion in this study. AAC was evaluated using two methods, AAC score and AAC length, based on the results of standing lateral abdominal radiography examinations.

What are the possible benefits and risks of participating?
There are no direct benefits involved with participating. Risks relate to radiation, but they are relatively low.

Where is the study run from?
Yokohama Coty University Hospital (Japan)

When is the study starting and how long is it expected to run for?
January 2016 to March 2018

Who is funding the study?
The Japan Society for the Promotion of Science

Who is the main contact?
Jun Shirakawa, MD, PhD
jshira-tky@umin.ac.jp

Contact information

Type(s)
Scientific

Contact name
Dr Jun Shirakawa

ORCID ID
http://orcid.org/0000-0002-0822-8750

Contact details
Yokohama City University
Fuku-ura 3-9
Kanazawa-ku
Yokohama
Japan
236-0004
+81 (0)457872639
jshira-tky@umin.ac.jp

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
B180900053

Study information

Scientific Title
Association of abdominal aortic calcification with coronary artery disease or other factors in type 2 diabetes

Acronym
AAC in T2D

Study objectives
Abdominal aortic calcification is associated with cardiovascular disease morbidity in patients with type 2 diabetes

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/10/2018, Clinical Ethics Committee of Yokohama City University (Fuku-ura 3-9, Kanazawa-ku, Yokohama 236-0004, Japan; +81-45-370-7627; rinri@yokohama-cu.ac.jp), ref: B180900053

Study design
Retrospective cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
The subjects included Japanese type 2 diabetes patients who had been hospitalized at Yokohama City University Hospital between January 1, 2016, and March 31, 2018. The lateral view of an abdominal X-ray image obtained while each subject was in a standing position will be examined, and the AAC score and AAC length, corresponding to the area of calcific deposits in the anterior and posterior aortic wall for the L1-4 and L1-5 regions, respectively, measured. The

associations between the AAC scores and lengths and the presence of coronary artery disease, cerebral infarction, and peripheral artery disease are then assessed. The correlation between the AAC grades and other clinical factors are also evaluated.

Intervention Type
Other

Primary outcome measure
Measured using patient records at the time of data collection:
1. AAC score
2. AAC length
3. Presence of cardiovascular diseases, such as CAD, CI, and PAD

Secondary outcome measures
Factors associated with AAC score or AAC length measured using patient records at the time of data collection

Overall study start date
15/10/2018

Completion date
02/12/2018

Eligibility

Key inclusion criteria
1. Japanese type 2 diabetes patients who had been hospitalized at Yokohama City University Hospital between January 1, 2016, and March 31, 2018.
2. Aged 20 years or older
2. Undergone a standing lateral abdominal radiography examination between 2 months before and 2 months after admission

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
285

Total final enrolment
285

Key exclusion criteria
1. Severe hepatic disorders
2. Psychiatric disorders
3. Cancers
4. Severe ketosis, diabetic coma or precoma
5. Severe infections
6. Severe traumatic injuries
7. Pancreatic exocrine diseases
8. Hepatic cirrhosis
9. Endocrine diseases
10. Postoperative patients

Date of first enrolment
01/01/2016

Date of final enrolment
31/03/2018

Locations

Countries of recruitment
Japan

Study participating centre
Yokohama City University Hospital
Fuku-ura 3-9
Kanazawa-ku
Yokohama
Japan
236-0004

Sponsor information

Organisation
Yokohama City University

Sponsor details
Fuku-ura 3-9
Kanazawa-ku
Yokohama
Japan
236-0004
+81 (0)457872639
jshira-tky@umin.ac.jp

Sponsor type
University/education

Website
http://www.yokohama-cu.ac.jp/index-e.html

Funder(s)

Funder type
Other

Funder Name
The Japan Society for the Promotion of Science

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request