ISRCTN11818569 https://doi.org/10.1186/ISRCTN11818569

Investigation of a high-risk group that should be considered for cognitive function testing in diabetes treatment

Submission date
29/08/2019

Recruitment status
No longer recruiting

Registration date
07/09/2019

Overall study status
Completed

Last Edited
10/12/2019

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
It is well known that the risk of cognitive disorder increases in diabetes patients, but there is no consensus regarding when patients should have a cognitive test or who should have the test. Because the cognitive test takes time, it is difficult to have a cognitive test for all diabetes patients. Searching the clinical parameters distinguished in diabetes patient saves time and effort. The aim of this study is to find out whether there is a high-risk group that should be considered for cognitive function testing in diabetes treatment.

Who can participate?
Patients with diabetes who were admitted to the Department of Diabetes and Metabolic Diseases at The University of Tokyo Hospital between 17/07/2016 and 31/03/2017.

What does the study involve?
Patient information is collected on the day of hospitalization and fasting blood samples are collected soon after obtaining informed consent.

What are the possible benefits and risks of participating?
The benefit is if the MMSE score has declined, the patient can have a medical examination of cognitive function, and can have treatment as quickly as possible. The risk is bleeding from blood collection.

Where is the study run from?
The University of Tokyo Hospital

When is the study starting and how long is it expected to run for?
The study was approved on 06/06/2016 and the recruitment was finished on 31/03/2017.

Who is funding the study?
University of Tokyo (Japan)

Who is the main contact?
Dr Yuka Kobayashi
kobayashiyu-int@h.u-tokyo.ac.jp

Contact information

Type(s)
Public

Contact name
Dr Yuka Kobayashi

Contact details
7-3-1 Hongo
Bunkyo-ku
Tokyo
Japan
1138655
+81 (0)3 5800 8815
kobayashiyu-int@h.u-tokyo.ac.jp

Additional identifiers

Protocol serial number
11171

Study information

Scientific Title
Which parameter is specific between normal cognitive function and declined cognitive function in diabetes patients?

Acronym
N/A

Study objectives
It is well known that the risk of cognitive disorder increases in diabetes patients. But, there is no consensus when patients should have a cognitive test or who should have the test. Because a cognitive test takes time, it is difficult to have a cognitive test for all diabetes patients. Searching the clinical parameters distinguished in diabetes patients saves time and effort.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/06/2016, Ethics Committee of the University of Tokyo (Office for Human Research Studies (OHRS), Graduate School of Medicine and Faculty of Medicine, The University of Tokyo, Faculty of Medicine Bldg.2 4F 7-3-1, Hongo, Bunkyo-ku, Tokyo 113-0033, Japan; Tel: +81 (0)3 5841 0818; Email: ethics@m.u-tokyo.ac.jp), No. 11171

Primary study design
Observational

Study design
Single-center observational cross-sectional study

Study type(s)
Screening

Health condition(s) or problem(s) studied
Diabetes mellitus

Interventions
The researchers investigated the following parameters: sex, age, disease duration, body mass index (BMI), smoking, alcohol consumption, family history of diabetes mellitus, coronary artery disease, stroke, neuropathy, retinopathy, nephropathy, systolic blood pressure (SBP), diastolic blood pressure (DBP), pulse pressure, diabetic treatment, use of antihypertensive drugs, use of lipid-lowering drugs, HbA1c, glycoalbumin (GA), GA/HbA1c ratio, homeostasis model assessment-insulin resistance (HOMA-IR), fasting C-peptide immunoreactivity (CPR), 2-h-after-meal CPR, C-peptide Index (CPI), fasting plasma glucose (FPG), serum albumin (Alb), uric acid (UA), triglycerides (TG), calculated LDL cholesterol (c-LDL), blood urea nitrogen (BUN), creatinine (Cre), estimated glomerular filtration rate (eGFR), HNA% and Mini Mental State Examination (MMSE) score. Doctors and nurses answered a questionnaire which percent they think the patient has cognitive dysfunction before knowing the MMSE score. Neuropathy was diagnosed when the patient has at least one of the following findings: (1) coefficient of variation of R-R intervals (CVR-R) under 2%, (2) reduction in Achilles tendon reflex, (3) decreased lower limb vibration sensing, (4) and the presence of obvious sensory impairment. Retinopathy was diagnosed and classified into normal (-), simple diabetic retinopathy (SDR), pre-proliferative diabetic retinopathy (PPDR), or proliferative diabetic retinopathy (PDR), according to the Davis classification. Nephropathy stage was determined by urinary albumin excretion and eGFR, according to the Classification of Diabetic Nephropathy 2014 proposed by the Joint Committee on Diabetic Nephropathy in Japan. Patient background information was collected on the day of hospitalization and fasting blood samples were collected soon after obtaining informed consent.

Intervention Type
Other

Primary outcome(s)
Cognitive dysfunction is measured using the Mini Mental State Examination (MMSE) score after getting consent.

Key secondary outcome(s)
Oxidative stress is measured using human non-mercaptalbumin (HNA%) from a morning blood test taken on the first day after getting consent.

Completion date
31/12/2018

Eligibility

Key inclusion criteria
Inpatients diagnosed with diabetes mellitus, who were admitted to the Department of Diabetes and Metabolic Diseases at The University of Tokyo Hospital between 17/07/2016 and 31/03/2017

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
200

Key exclusion criteria
1. Pregnant
2. Lactating
3. Acute organ failure (e.g., pneumonia, acute myocardial infarction, acute cerebral infarction, diabetic ketoacidosis, and hyperosmolar hyperglycemic state)
4. Congenital cognitive disorders

Date of first enrolment
17/07/2016

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
Japan

Study participating centre
Tokyo University Hospital
7-3-1 Hongo, Bunkyo-ku
Tokyo
Japan
1138655

Sponsor information

Organisation
University of Tokyo

ROR
https://ror.org/057zh3y96

Funder(s)

Funder type
University/education

Funder Name
University of Tokyo

Alternative Name(s)
University of Tokyo in Japan, The University of Tokyo, , , , UTokyo

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Japan

Funder Name
Nakatani Foundation for Advancement of Measuring Technologies in Biomedical Engineering

Alternative Name(s)
Nakatani Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Japan

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Yuka Kobayashi (yukaodawara@aol.com or kobayashiyu-int@h.u-tokyo.ac.jp).

IPD sharing plan summary

Available on request