

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

<b>Submission date</b> 29/08/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 07/09/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/12/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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**  
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## 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

## Study design

Single-center observational cross-sectional study

## Primary study design

Observational

## 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)**

The University of Tokyo, , , , Utokyo

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**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