# Renal structure and function in type 2 diabetes

| Submission date   | Recruitment status                | <ul><li>Prospectively registered</li></ul>    |
|-------------------|-----------------------------------|-----------------------------------------------|
| 08/02/2011        | No longer recruiting              | <pre>Protocol</pre>                           |
| Registration date | Overall study status              | Statistical analysis plan                     |
| 17/02/2011        | Completed                         | Results                                       |
| Last Edited       | Condition category                | Individual participant data                   |
| 17/02/2011        | Nutritional, Metabolic, Endocrine | <ul><li>Record updated in last year</li></ul> |

### Plain English summary of protocol

Not provided at time of registration

# Contact information

### Type(s)

Scientific

#### Contact name

Dr Tatsumi Moriya

### Contact details

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# Additional identifiers

Protocol serial number

N/A

# Study information

#### Scientific Title

Renal structure and function in type 2 diabetes: an observational, longitudinal case-control and single-centred study

### **Study objectives**

Little is known about the relationships between renal structural changes and the glomerular filtration rate (GFR). To elucidate renal structural-functional relationships in the early stage of diabetic nephropathy in type 2 diabetes, we performed a detailed analysis of renal morphology

and its relationship with GFR. Finally, we studied whether glomerular hyperfiltration can predict further functional changes.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Research Ethics Committee of Kitasato University School of Medicine approved on the 22nd April 2004 (ref: B04-02)

### Study design

Observational longitudinal case-control single-centre study

### Primary study design

Observational

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Diabetic nephropathy, renal structural changes

#### **Interventions**

Thirty type 2 diabetic patients showing either normoalbuminuria or microalbuminuria participated. Microscopic morphometric analyses provided quantitative glomerular structural changes. Patients were followed every 6 months for an average of  $6.2 \pm 3.5$  years and glomerular filtration rate was determined.

### Intervention Type

Other

#### **Phase**

Not Applicable

### Primary outcome(s)

The GFR measured by the plasma clearance of unlabeled iohexol. The plasma concentration of iohexol was measured by HPLC. Measured every 6 months after renal biopsy.

## Key secondary outcome(s))

The urinary albumin measured by turbidimetric immunoassay. Measured every 6 months after renal biopsy.

## Completion date

31/03/2008

# Eligibility

# Key inclusion criteria

- 1. Normotensive type 2 diabetic patients
- 2. Without overt proteinuria, haematuria or renal dysfunction

- 3. Without any evidence suggesting atherosclerotic diseases
- 4. Living kidney donors served as healthy controls
- 5. Aged 20 65 years, either sex

### Participant type(s)

**Patient** 

### Healthy volunteers allowed

No

### Age group

Adult

#### Sex

All

### Key exclusion criteria

- 1. Receiving antihypertensive drugs
- 2. With a past history of any malignant, cerebrovascular or cardiovascular disease
- 3. With recurrent infection

### Date of first enrolment

01/04/1998

#### Date of final enrolment

31/03/2008

# Locations

#### Countries of recruitment

Japan

### Study participating centre Endocrinology, Diabetes and Metabolism Sagamihara Japan 252-0374

# Sponsor information

### Organisation

Kitasato University School of Medicine (Japan)

#### **ROR**

https://ror.org/00f2txz25

# Funder(s)

## Funder type

Research organisation

### Funder Name

Kitasato University Alumni Association (Japan) - pays incidental costs

# **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration