

Renal structure and function in type 2 diabetes

Submission date 08/02/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 17/02/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/02/2011	Condition category 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
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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 ± 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