Renal structure and function in type 2 diabetes

Submission date	Recruitment status	Prospectively registered
08/02/2011	No longer recruiting	∐ Protocol
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	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/04/1998

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

Age group

Adult

Sex

Both

Target number of participants

50

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)

Sponsor details

c/o Dr Tatsumi Moriya Endocrinology, Diabetes and Metabolism 1-15-1 Kitasato, Minami-ku Sagamihara Japan 252-0374

Sponsor type

University/education

Website

http://www.kitasato-u.ac.jp/

ROR

https://ror.org/00f2txz25

Funder(s)

Funder type

Research organisation

Funder Name

Kitasato University Alumni Association (Japan) - pays incidental costs

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date
Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration