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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

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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 ± 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
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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 summary
Not provided at time of registration