

Renal artery stenosis in patients with diabetes

Submission date 05/06/2012	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 18/06/2012	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 29/09/2014	Condition category Circulatory System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Renal artery stenosis (RAS) is a narrowing of the arteries that carry blood to one or both of the kidneys. It is associated with an increased risk of high blood pressure and progression of kidney disease. However, in clinical practice, the presence of renal artery stenosis may be difficult to distinguish in patients with type 2 diabetes with kidney disease. This study was designed to find out about the prevalence of previously undetected renal artery stenosis in a group of South Asian patients with type 2 diabetes undergoing angiography for investigation of heart disease, and to find clinical characteristics that may aid in the identification of these patients.

Who can participate?

Patients with type 2 diabetes who are undergoing coronary angiography.

What does the study involve?

All recruited patients will have a renal angiography carried out at the same sitting as a coronary angiography.

What are the possible benefits and risks of participating?

There will be no immediate direct benefit to those taking part.

Where is the study run from?

Inlaks & Budhram Hospital, Pune, India.

When is the study starting and how long is it expected to run for?

The study started in January 2008 and ended in December 2008.

Who is funding the study?

Inlaks & Budhram Hospital, Pune, India

Who is the main contact?

Dr Eberta Tan
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Contact information

Type(s)

Scientific

Contact name

Dr Roy Debajyoti

Contact details

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Prevalence and risk factors of renal artery stenosis in South Asian patients with type 2 diabetes using renal angiography

Study objectives

To determine the prevalence and risk factors of renal artery stenosis (RAS) in patients with type 2 diabetes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Board of Inlak Budhram Hospital, Pune, India, December 2007

Study design

Cohort study

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

Renal artery stenosis in patients with type 2 diabetes

Interventions

Statistical analysis

The characteristics of patients with RAS were compared to those without RAS using Student's t-tests for continuous variables and Chi-Square or Fisher tests for comparison of categorical variables as appropriate. Univariate logistic regressions were performed to identify the factors

associated with the presence of RAS. From the significant variables identified at this step, the backward stepwise method was used to identify variables that were independently associated with the outcome using the likelihood ratio test. Odds ratios and their corresponding 95% confidence intervals were presented as effect size. Tests for the appropriate assumptions for the models were carried out. Data was analyzed using SAS v9.2 (SAS Institute Inc., Cary, NC, USA) and the level of significance was set at 5%.

Total duration of follow-up: 1 day

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Prevalence of renal artery stenosis

Key secondary outcome(s)

Risk factors of renal artery stenosis

Completion date

31/12/2008

Eligibility

Key inclusion criteria

All consecutive patients with type 2 diabetes who underwent coronary angiography and who gave informed consent to be screened for renal artery stenosis at the same time were recruited into the study. The decision for coronary angiography was made by the consulting cardiologist based on a clinical indication of either symptomatic angina, ST-T alterations on the electrocardiogram or an acute myocardial infarction.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients with known vasculitis
2. Renal artery stenosis
3. A serum creatinine level of >3.0 mg/dl or on renal replacement therapy

Date of first enrolment

01/01/2008

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

India

Singapore

Study participating centre

2 Simei Street 3

Singapore

Singapore

529889

Sponsor information

Organisation

Changi General Hospital (Singapore)

ROR

<https://ror.org/02q854y08>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Inlak Budhram Hospital (India)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration