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# Renal artery stenosis in patients with diabetes

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| **Submission date**<br>05/06/2012 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>18/06/2012 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>29/09/2014 | **Condition category**<br>Circulatory System | [_] Individual participant data<br>[_] 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

# 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

### Primary study design
Observational

### Study design
Cohort study

### 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