# Renal artery stenosis in patients with diabetes

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

### 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 Eberta\_Tan@cgh.com.sg

# Contact information

### Type(s)

Scientific

#### Contact name

Dr Roy Debajyoti

#### Contact details

2 Simei Street 3 Singapore Singapore 529889

# 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 ttests 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

## **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes