

Renal artery stenosis in patients with diabetes

Submission date 05/06/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/06/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/09/2014	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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Contact details

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529889

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Prevalence of renal artery stenosis

Secondary outcome measures

Risk factors of renal artery stenosis

Overall study start date

01/01/2008

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

Age group

Adult

Sex

Both

Target number of participants

249

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)

Sponsor details

2 Simei Street 3
Singapore
Singapore
529889

Sponsor type

Hospital/treatment centre

ROR

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

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Inlak Budhram Hospital (India)

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