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# Renovascular hypertension: the role of angioplasty after selecting patients according to the doppler resistive index

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| **Submission date**<br>26/09/2005 | **Recruitment status**<br>Stopped | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>26/09/2005 | **Overall study status**<br>Stopped | |
| **Last Edited**<br>25/02/2009 | **Condition category**<br>Circulatory System | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
MCT-52685

## Study information

**Scientific Title**

The role of angioplasty after selecting patients according to the doppler resistive index: a randomised controlled trial

## Study objectives
Medical treatment and renal angioplasty in renovascular hypertension

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Comite d'ethique de la recherche, Hopital Notre Dame, Centre Hospitalier de L'universite de Montreal (CHUM), Montreal, Québec approved on 14th May 2002.

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Renovascular hypertension

## Interventions
Added 25/02/2009: the study was terminated early due to recruitment issue.

Inclusion of patients presenting a controlled hypertension with 2 or 3 antihypertensive drugs and risk factors for renovascular hypertension. Selection on Doppler inclusion criteria (Resistive index less than 0.75) and renal angiography renal artery stenosis of more than 60% in diameter.

Group 1: Medical treatment (duration: 12 months)
Group 2: Renal angioplasty

Follow up for one year following angioplasty.

Trial details received: 12 Sept 2005

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome(s)
Systolic and diastolic blood pressure 12 months post-randomisation

## Key secondary outcome(s)
1. Blood pressure at 1 and 6 months post-randomisation
2. Clinical success on blood pressure control at 12 months

3. Serum creatine clearance when off antihypertensive drugs during 12 months? Does it mean that you have no control over those?
4. Morbidity related to cardiovascular events during follow-up
5. Incidence of renal artery restenosis

### Completion date
30/03/2006

### Reason abandoned (if study stopped)
Participant recruitment issue

## Eligibility

### Key inclusion criteria
1. Hypertension greater than 140/90 mmHg with two hypertensive drugs
2. Hypertension less than 140/90 mmHg with three antihypertensive drugs
3. Aged greater than or equal to 30 years old, either sex
4. Atherosclerotic renal artery stenosis of more than 60% on catheter angiography or 70% on computed tomography (CT) or magnetic resonance (MR) angiography
5. Doppler resistive index less than 0.75

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. Creatinine clearance less than 30 ml/min
2. Non controlled hypertension (greater than 160/105 mmHg) despite 3 anti-hypertensive drugs
3. Renal artery stenosis greater than 95%
4. Fibromuscular dysplasia

### Date of first enrolment
01/09/2002

### Date of final enrolment
30/03/2006

## Locations

### Countries of recruitment
Canada

**Study participating centre**
**CHUM-Notre-Dame**
Montréal
Canada
H2L 4M1

# Sponsor information

**Organisation**
Hospital Notre-Dame (Montréal) (Canada)

**ROR**
https://ror.org/01w7qz648

# Funder(s)

**Funder type**
Research organisation

**Funder Name**
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-52685)

# 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? |
|---|---|---|---|---|---|
| Results article | cost-benefit analysis results | 01/03/2005 | | Yes | No |