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

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