ISRCTN65752530 https://doi.org/10.1186/ISRCTN65752530

Renin Angiotensin SyStem blockade: diabetes nephropathy

Submission date	Recruitment status	[_] Prospectively registered
19/07/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/07/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/10/2021	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Bernard Zinman

Contact details
Leadership Sinai Centre for Diabetes
Lebovic Building
5th Floor, L5-024
Mount Sinai Hospital
600 University Avenue
Toronto, ON
Canada
M5G 1X5
+1 416 586 8747
zinman@mshri.on.ca

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT00143949

Secondary identifying numbers
DCT-14281

Study information

Scientific Title
Renin Angiotensin SyStem blockade: diabetes nephropathy

Acronym
RASS

Study objectives
Inhibition of the renin angiotensin system will protect the kidney.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Mount Sinai research ethics board

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Diabetic Nephropathy (DN)

Interventions
1. Angiotensin-Converting Enzyme (ACE) inhibitor: Enalapril
2. Angiotensin Receptor Blocker: Losarten

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Enalapril, Losarten

Primary outcome measure
The primary outcome is to determine, in Type one diabetes without clinical evidence of diabetic nephropathy, if inhibition of the renin-angiotensin system activity can prevent or retard the rate of development of the histologic lesions associated with diabetic nephropathy.

Secondary outcome measures
1. Retinopathy
2. Microalbuminuria
3. Blood pressure
4. GFR
5. Creatinine

Overall study start date
01/03/1997

Completion date
01/03/2007

Eligibility

Key inclusion criteria
1. Patients with type one diabetes
2. Normal Glomerular Filtration Rate (GFR) and Blood Pressure (BP)
3. Normoalbuminuria
4. Either sex, 18 to 64 years of age

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
285

Total final enrolment
223

Key exclusion criteria
1. Type one Diabetes Mellitus longer then 20 years
2. BP more than 135/85 mmHg

3. GFR less than 90 ml/min
4. Microalbuminuria
5. Soiltary kidney
6. Other chronic disease
7. Pregnancy or planning pregnancy within two years of randomisation

Date of first enrolment
01/03/1997

Date of final enrolment
01/03/2007

Locations

Countries of recruitment
Canada

Study participating centre
Leadership Sinai Centre for Diabetes
Toronto, ON
Canada
M5G 1X5

Sponsor information

Organisation
Canadian Institutes of Health Research (CIHR) (Canada)

Sponsor details
Room 97
160 Elgin Street
Address locator: 4809A
Ottawa, ON
Canada
K1A OW9
+1 888 603 4178
info@cihr-irsc.gc.ca

Sponsor type
Research organisation

Website
http://www.cihr-irsc.gc.ca/

ROR

https://ror.org/01gavpb45

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: DCT-14281)

Funder Name
Merck Frosst Canada & Co (Canada)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		01/08/2011	27/10/2021	Yes	No