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Do vitamins for homocyst(e)ine slow progression of diabetic nephropathy?

Submission date	Recruitment status	[_] Prospectively registered
01/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/04/2010	Urological and Genital Diseases	

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-41551

Study information

Scientific Title

Lowering total homocysteine using vitamins to slow the progression of diabetic nephropathy: a randomised controlled trial

Acronym
DIVINe

Study objectives
To test whether lowering total homocysteine with vitamins slows progression of diabetic nephropathy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Western Ontario, Office of Research Ethics approved on the 31st May 2005

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetic nephropathy

Interventions
Placebo versus active vitamin combination tablet once daily.

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vitamins

Primary outcome(s)
The change in glomerular filtration rate (GFR)

Key secondary outcome(s)
1. Renal outcomes (change from baseline in urea, creatinine, urinary albumin excretion, creatinine clearance, and progression to dialysis or transplantation)
2. Vascular events (stroke, death, myocardial infarction, revascularisation)
3. Cognitive decline
4. Progression of carotid intima-media thickness and plaque volume (London study centre only)

Completion date
30/09/2005

Eligibility

Key inclusion criteria
1. Type I or type II diabetes mellitus
2. Clinical or histological diagnosis of diabetic nephropathy
3. Urinary albumin excretion level of at least 300 mg/day or urinary protein level of at least 500 mg/day (based upon a 24 hour urine collection) within the past 24 months
4. Patient is able and willing to give informed consent
5. Over the age of 18 years old, either sex
6. Individual patient co-operation is obtained for regular follow-up until completion of the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patient starting on an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker who has been taking the drug for less than three months. (After a three-month time period the patient may then be considered eligible for the trial).
2. Patient not expected to survive three years because of intercurrent cancer or other severe illness
3. Patient expected to be non-compliant; who will not adhere to the study visit protocol, who will not take the study vitamins or who will not discontinue previous multivitamin or B-complex vitamin use
4. Patient on dialysis or imminently expected to require dialysis
5. Other known renal disease that may impact on progression rate (i.e. renal artery stenosis or glomerular renal disease such as membranous nephropathy)
6. Women of childbearing potential who are unwilling to practice a form of birth control for the duration on the trial deemed appropriate by the Investigator
7. Patient with a creatinine clearance of less than 30 ml/min based on the Cockcroft-Gault method or less than 25 ml/min if the patient is currently on an ACE inhibitor or angiotensin receptor blocker (within 30 days prior to randomization if less than 35 ml/min or within 6 months if greater than or equal to 35 ml/min)

Date of first enrolment
01/10/2000

Date of final enrolment
30/09/2005

Locations

Countries of recruitment
Canada

Study participating centre
Stroke Prev. & Ath. Research Centre
London, Ontario
Canada
N6G 2V2

Sponsor information

Organisation
John P. Robarts Research Institute (Canada)

ROR
https://ror.org/02grkyz14

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-41551)

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	results	28/04/2010		Yes	No