

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

Submission date 01/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 01/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/04/2010	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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