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DREAM3 - Diabetes Risk Evaluation and Microalbuminuria in Saskatchewan First Nations Peoples

Submission date	Recruitment status
09/09/2005	No longer recruiting
Registration date	**Overall study status**
09/09/2005	Completed
Last Edited	**Condition category**
03/10/2017	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Sheldon William Tobe

Contact details
Sunnybrook & Women's College Health Sciences Ctre
Room A240
2075 Bayview Avenue
Toronto
Canada
M4N 3M5
+1 416-480-6901
sheldon.tobe@sw.ca

Additional identifiers

Protocol serial number
DCT-52188

Study information

Scientific Title

DREAM3 - Diabetes Risk Evaluation and Microalbuminuria in Saskatchewan First Nations Peoples: a randomised controlled trial

Acronym
DREAM3

Study objectives
The DREAM3 study was designed to evaluate the effectiveness of an algorithm of pharmocologic therapy implemented by the home care nurse in a community setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Board of the Sunnybrook and Women's College, 13 August, 2001

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hypertension with diabetes

Interventions
Participants were randomized to either the 1st Nations nurse-administered stepped protocol drug approach or to usual care. The nurse administered stepped protocol approach will involve adding three medications, one at a time, until either the BP is controlled to target (<130/80 mmHg) or the patient is at the maximum dose and number of medications as described in the algorithm. Treatment arm patients will be asked to see their family physicians to review medication changes. The nurse will assess patients in both groups at each visit in the same way. All patient specific advice from each visit will be forwarded to the patients family physicians for both groups. In the usual care group, this information will be sent to the patients primary care physician and the patient will be advised to follow-up with their primary care physician for any required treatment. The nursing assessments will be in addition to the health care the patients normally receive.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Mean change in Systolic Blood Pressure from baseline to final visit at 12 months.

Key secondary outcome(s)

All at 12 months:
1. Change in diastolic blood pressure between the two groups
2. Changes in urine albumin status
3. Proportion of patients achieving blood pressure targets
4. Adverse events

Completion date
01/03/2004

Eligibility

Key inclusion criteria
Eligible patients were Status Indians with the BTCIHS, age 18 or over (either sex), diagnosed with type 2 diabetes and persistent hypertension (greater than or equal too 130/80 mmHg).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Exclusion criteria included the use of beta-blockers, and women of childbearing age not able to use a reliable method of birth control and an inability to follow protocol.

Date of first enrolment
21/11/2001

Date of final enrolment
01/03/2004

Locations

Countries of recruitment
Canada

Study participating centre
Sunnybrook & Women's College Health Sciences Ctre
Toronto

Canada
M4N 3M5

Sponsor information

Organisation
Sunnybrook and Women's College Health Sciences Ctr (Canada)

ROR
https://ror.org/03wefcv03

Funder(s)

Funder type
Industry

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: DCT-52188)

Funder Name
Pfizer (Canada)

Alternative Name(s)
Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen, Pfizer Inc

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/04/2006		Yes	No