

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

Submission date
09/09/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
09/09/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
03/10/2017

Condition category
Nutritional, Metabolic, Endocrine

☐ 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 pharmacologic 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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Mean change in Systolic Blood Pressure from baseline to final visit at 12 months.

Secondary outcome measures

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

Overall study start date

21/11/2001

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

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)

Sponsor details

2075 Bayview Avenue

Toronto

Canada

M4N 3M5

Sponsor type

Hospital/treatment centre

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

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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	25/04/2006		Yes	No