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A structured approach to home glucose monitoring for type 2 diabetes patients using insulin

Submission date
10/01/2017

Recruitment status
No longer recruiting

Registration date
16/01/2017

Overall study status
Completed

Last Edited
12/01/2017

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (T2DM) is a long term condition where sufferers have difficulty controlling their blood sugar (glucose) as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). If left untreated, high blood sugar levels can lead to a range of serious complications, such as damage to the eyes, kidneys and nervous system. Effective blood sugar control is essential to prevent these complications from developing. One way of doing this is through monitoring blood sugar levels. Gyclated haemoglobin is a form of haemoglobin (the protein in red blood cells that binds to oxygen). By measuring glycated haemoglobin levels, it is possible to monitor long-term blood sugar control (around three months, which is the life cycle of a red blood cell). Research has shown that decreasing HbA1c helps to reduce risk of diabetes complications. The aim of this study is to find out if a structured blood sugar monitoring program can help improve long-term blood sugar control.

Who can participate?
Adults who have had type 2 diabetes for at least one year who are currently being treated with insulin injections.

What does the study involve?
All participants are asked to test their blood sugar levels at home at certain times of the day for three days a week for a total of six months. Participants visit the diabetes out-patient clinic at the hospital once each month, where doctors look at their blood sugar readings and determine how to change their insulin doses. At the beginning of the study and after three and six months, glycated haemoglobin is tested in order to assess whether the monitoring has helped improve overall blood sugar control.

What are the possible benefits and risks of participating?
The benefits of participating in this research may be an improvement to overall blood sugar control, however this cannot be guaranteed. Since the trial doctor may increase patient insulin doses depending on the results from their monitoring, there is a small risk that blood sugar

levels may become too low. This type of side effect is usually mild and may include symptoms such as cold sweats, hunger, headache, feeling sick, changes in vision, light-headedness, feeling sleepy, nervousness, anxiety, fast heartbeat, slight shaking, weakness and difficulties concentrating. In rare cases, this may be more severe ad may lead to unconsciousness and even death. Blood testing (finger-prick and laboratory blood sampling) is part of normal diabetes care, but there might be some discomfort due to more frequent blood testing during the study.

Where is the study run from?
1. Kalafong District Hospital (South Africa)
2. Steve Biko Academic Hospital (South Africa)

When is the study starting and how long is it expected to run for?
October 2014 to October 2015

Who is funding the study?
1. Roche Diagnostics (South Africa)
2. Faculty of Health Sciences, University of Pretoria (South Africa)
3. South African National Research Foundation (South Africa)

Who is the main contact?
1. Miss Kerry Kalweit (public)
k.kalweit@live.com
2. Professor Paul Rheeder (scientific)
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
DOH-27-0115-4949

Study information

Scientific Title
The effect of a structured self-monitoring blood glucose regimen on glycaemic control for type 2 diabetes patients using insulin

Study objectives
Thea aim of this study is to assess the efficacy of structured blood glucose testing in guiding an insulin titration algorithm in poorly controlled, insulin-treated type 2 diabetes patients as per change in HbA1c over 6 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Faculty of Health Sciences Research Ethics Committee of the University of Pretoria, 30/10/2014, ref: 432/2014

Primary study design
Interventional

Study design
Non-randomised single-group open uncontrolled efficacy study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions

Participants are asked to perform four blood glucose tests for three consecutive days of each week. On each of the self-monitoring of blood glucose (SMBG) days, a fasting breakfast and bed-time glucose test is performed. Each alternative week, the patient also performs either a fasting lunch time or fasting dinner time glucose test. For the fourth test each day, the patient alternates between one post-breakfast, and two post-lunch or two post-dinner glucose tests. SMBG testing is staggered on different days of the week throughout the month to cover weekdays and weekends. This results in a total of 48 blood glucose tests per month over a total period of six months. Participants see their diabetes physician once a month for medication adjustments based on SMBG values according to the validated insulin titration schedule.

Intervention Type
Behavioural

Primary outcome(s)
Glycated hemoglobin (HbA1c) is measured using the Cobus B101 (Roche Products, South Africa) at baseline, 3 and 6 months.

Key secondary outcome(s)
1. Total daily insulin dose is measured by recording number of international units of insulin per day at baseline, 1, 2, 3, 4, 5 and 6 months
2. Glycaemic variability is measured using standard deviation of SMBG data at baseline, 1, 2, 3, 4, 5 and 6 months"
3. Mean fasting plasma glucose (FPG) is measured using by calculating the mean of SMBG tests performed before breakfast for each month at baseline, 1, 2, 3, 4, 5 and 6 months
4. Mean post-prandial glucose (PPG) values is measured by calculating the difference in 12 paired pre- and post-meal blood glucose values for each month at baseline, 1, 2, 3, 4, 5 and 6 months
5. Overall efficacy is measured by recording the proportion of patients reaching an HbA1c target <7.0% (53 mmol/mol) at 6 months
6. Hypoglycaemic event rate is calculated as [(total number of SMBG <4.0mmol/L across all participants) / (total duration of treatment in years across all participants)] at 6 months
7. Weight is measured using a digital scale at baseline, 1, 2, 3, 4, 5 and 6 months
8. Compliance to SMBG protocol is measured by recording the total number of SMBG tests performed out of a maximum of 288 throughout the study period at 6 months

Completion date
26/10/2015

Eligibility

Key inclusion criteria
1. Duration of type 2 diabetes >1 year
2. Aged 18 to 75 years
3. HbA1c ≥ 8.5% (69.4 mmol/mol)
4. Currently treated with ≥ 1 insulin injection per day
5. Voluntarily signing the informed consent document

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Type 1 diabetes
2. Participation in any other research protocol within the last 30 days
3. Current use of oral hypoglycaemic agents other than Metformin
4. History of cancer within the last five years
5. Currently treated with chemotherapy or radiation therapy
6. Plans to relocate or travel extensively during the following six months
7. Pregnant or breast feeding
8. One or more severe hypoglycaemic episode(s) within the previous six months that resulted in hospital admission and/or coma
9. Severe depression or other severe psychological conditions
10. History of chronic kidney disease
11. History of heart failure where cardiovascular status is unstable
12. Manual or visual disability that required dependency on others to give insulin or to document blood glucose values
13. Major surgery scheduled within six months of enrolment
14. Current use of oral corticosteroids

Date of first enrolment
26/01/2015

Date of final enrolment
01/04/2015

Locations

Countries of recruitment
South Africa

Study participating centre
Kalafong District Hospital
1 Klipspringer Street
Pretoria
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Study participating centre
Steve Biko Academic Hospital
Dr Savage Road
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Sponsor information

Organisation
University of Pretoria

ROR
https://ror.org/00g0p6g84

Funder(s)

Funder type
Industry

Funder Name
Roche Diagnostics

Funder Name
Faculty of Health Sciences, University of Pretoria

Funder Name
South African National Research Foundation

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Kerry Kalweit (k.kalweit@live.com)

IPD sharing plan summary
Available on request