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Glycaemic control and prevention of hypoglycaemia in intensively treated subjects with type 1 diabetes using Accu-Chek® advisor insulin guidance software

Submission date
31/10/2007

Recruitment status
No longer recruiting

Registration date
06/11/2007

Overall study status
Completed

Last Edited
24/05/2019

Condition category
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

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Additional identifiers

Protocol serial number
03-0834

Study information

Scientific Title

Glycaemic control and prevention of hypoglycaemia in intensively treated subjects with type 1 diabetes using Accu-Chek® advisor insulin guidance software

Acronym
N/A

Study objectives
Improvement in glucose control by at least 0.4% reduction in haemoglobin A1c (HbA1c) values in subjects using insulin guidance software at 6 months and 1 year.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Colorado Multiple Institution Review Board (COMIRB) University of Colorado at Denver Health Sciences Center, first on the 13th December 2004, and thereafter annual reviewed by COMIRB (ref: 04-0834).

Study design
Open-label randomised controlled trial involving 123 subjects with type 1 diabetes on multiple daily injections

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 1 Diabetes

Interventions
The primary outcome of this study was predefined as a reduction in HbA1c value of more than 0.4% in the experimental group.

Subjects randomised to the experimental group received a Personal Digital Assistant (PDA) loaded with the insulin guidance software. At baseline (visit 1), a healthcare provider and/or Certified Diabetes Educator (CDE) reviewed the features of the software on the PDA and loaded a subject specific insulin dosing algorithm into the software based on the physician's recommendations. The software program allowed the healthcare provider to enter demographic data such as age, height and weight which could potentially affect the insulin sensitivity factor already programmed into the device. The program advised basal, bolus and correction insulin dosages based on individual patients' prescriptions in addition to being alerted for Self Monitored Blood Glucose (SMBG) testing. Subjects in the experimental group were also asked to input their blood glucose values into the PDA via the touch screen. Subjects then received a recommended insulin dose based on their prescription which was programmed by the healthcare provider. The patients were asked to either agree with the recommended insulin dose or disagree, and manually enter the insulin dose they took for a given event. All the data from the glucose meters and the PDAs were downloaded at every visit.

Glucose values were captured in one of the following categories to assess target glycaemia and pie charts were created. Within Target Range (WTR) glucose values were those between 70 - 150 mg/dL (3.89 to 8.33 mmol/L). Below Target Range (BTR) glucose values were defined as 69 mg /dL (3.83 mmol/L) and Above Target Range (ATR) glucose values were those values above 150 mg/dL (8.33 mmol/L). These glucose levels were chosen based on our previous research on SMBG downloads.

Hypoglycaemia:
Hypoglycaemia was defined as glucose values of 59 mg/dL (3.27 mmol/L). Severe hypoglycaemia was defined as subjects needing assistance as previously described by DCCT Research Group.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
Improvement in glucose control by at least 0.4% reduction in HbA1c values in subjects using insulin guidance software at 6 months and 1 year.

Key secondary outcome(s))
Secondary outcomes were measured at each of the clinic visits given below for:
1. Hypoglycaemia
2. Weight gain
3. Insulin dose
4. Frequency of self monitoring of blood glucose, within, above and below the target range glycaemia (70 - 150 mg/dL)

All subjects were asked to attend seven in-clinic visits (baseline, 2 weeks, 6 weeks, 3 months, 6 months, 9 months and 12 months) and participate in three telephone visits (4.5 months, 7.5 months, 9.5 months) throughout the course of the study. Data for blood glucose values, testing frequency, hyperglycaemic excursions, hypoglycaemic events (all, nocturnal, and severe), insulin dose, weight and BMI, hospitalisations, emergency room visits and illnesses were recorded at each in clinic visit. All subjects completed a patient satisfaction questionnaire and the experimental group also completed an Advisor questionnaire.

As part of their routine clinical care, any additional phone visits were equally encouraged in both groups.

Completion date
05/01/2007

Eligibility

Key inclusion criteria
1. Adult - male or female, 18 to 60 years of age
2. Diagnosed with Type 1 diabetes mellitus at least six months

3. HbA1c greater than 7.5% and less than 11.0% at screening
4. Insulin dose 0.5 - 2.0 units/kg
5. Hematocrit between 25% and 65%
6. Weight 100 - 300 pounds
7. On a dual insulin therapy supported by Accu-Chek® insulin advisor software
8. On a "day shift" schedule (typical day begins before noon)
9. Willing to perform a minimum of three blood glucose tests per day - before breakfast, before lunch, and before dinner (standard of care)
10. Willing to complete at least 7 clinic visits in 12 months (baseline, 2-week, 6-week, 3-month, 6-month, 9-month, and 12-month)
11. Willing to complete three study phone calls conducted by study coordinator (4.5-month, 7.5-month and 10.5-month)
12. Able and willing to provide written informed consent to participate
13. Willing to comply with the study protocol
14. Willing to be randomised into either the control group or the experimental group

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
123

Key exclusion criteria
1. On insulin pump therapy
2. On oral, inhaled or pre-mixed insulin
3. Engaged in a minimum of 30 minutes of cardiovascular (aerobic) exercise 5 days out of a 7-day week
4. Conditions that can cause significant increase of the insulin sensitivity factor, such as a steroid therapy, diabetic ketosis, insulin-resistant syndrome
5. Creatinine greater than 2.5 mg/dl, renal transplantation or currently undergoing kidney dialysis
6. Pregnant or intends to become pregnant during the course of the study
7. Undergoing therapy for a malignancy, other than basal cell or squamous cell skin cancer
8. Plan to travel to a different time zone more than three times per month
9. Clinical signs or symptoms of liver disease such as jaundice
10. Diagnosis of acute or chronic hepatitis
11. Diagnosis of haemoglobinopathy or chronic anaemia
12. Severe unexplained hypoglycaemia in the past 3 months that required Emergency Department (ED) admission

13. Participation in another clinical trial in the past 1 month
14. Weight under 100 pounds or over 300 pounds

Date of first enrolment
07/01/2005

Date of final enrolment
05/01/2007

Locations

Countries of recruitment
United States of America

Study participating centre
1775 N. Ursula Street
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Sponsor information

Organisation
Roche Diagnostics Corporation (USA)

ROR
https://ror.org/011qkaj49

Funder(s)

Funder type
Government

Funder Name
State of Colorado Public Health and Environment (USA) (grant ref: 08 FLA 00250)

Funder Name
National Institutes of Health (NIH) (USA) - Diabetes Endocrine Research Center (grant ref: P30 DK575616)

Funder Name
National Institutes of Health (NIH) (USA) - General Clinical Research Centers Program (grant ref: M01 RR0069)

Funder Name
Children's Diabetes Foundation (USA) (grant refs: R01 HL61753, RO1 HL079611 and RO1 DK32493)

Funder Name
Roche Diagnostics Corporation (USA) - funding from Roche for this research was provided directly to the University of Colorado at Denver Health Sciences Center

Funder Name
This protocol was written and developed by Satish K. Garg, MD at the Barbara Davis Center for Childhood Diabetes at the University of Colorado at Denver Health Sciences Center (USA).

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	01/10/2008	24/05/2019	Yes	No