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Analysis of a messaging service to support patients with type 2 diabetes on basal insulin therapy

Submission date
05/08/2020

Recruitment status
No longer recruiting

Registration date
14/08/2020

Overall study status
Completed

Last Edited
12/12/2022

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 (T2D) often requires the use of insulin to keep blood sugar levels under control. Basal insulin-supported oral therapy (BOT) is a clinically valid and useful approach for the management of T2D. BOT is started with active insulin dose titration, which involves self-monitoring of the fasting blood glucose (FBG) and adjusting the dose of the once-daily long-acting (basal) insulin accordingly until target glucose levels are reached. The titration is typically initiated and supervised by a healthcare professional (HCP) and follows the default scheme described by the insulin manufacturer. However, HCPs can deviate from the manufacturer recommendations based on the individual needs of the person with diabetes (PwD). The GetFit short messaging service is a new telemedical approach to basal insulin titration developed by Roche Diabetes Care. After initiation of the GetFit service by an HCP during a patient visit, the service can be used to titrate the user to his/her individual optimum basal insulin dose. The aim of this study is to test the effectiveness of the GetFit supported titration of once-daily long-acting (basal) insulin in patients with T2D.

Who can participate?
Patients with T2D with sub-optimal blood sugar control on non-insulin therapy who are planned to be treated with BOT

What does the study involve?
In the study, titration of once-daily, long-acting insulin will be supported by using the investigational device, the RocheDiabetes InsulinStart service for about 4.5 months (18 weeks). During the study, participants are supported by the GetFit service to titrate to their individual optimal insulin dose for reaching their target FBG level. After 16 weeks the effectiveness of the therapy is evaluated.

What are the possible benefits and risks of participating?
During participation in this study, participants may encounter the known potential risks of the BOT therapy (HbA1c determination, BG measurement, insulin administration). These risks are an integral part of diabetes therapy and applied in daily practice. The participants may experience

the following potential benefits while participating in this study. The GetFit service, the BG meter and lancing device including the consumables needed for the study procedures will be provided at no charge to the subjects. Costs for SMS will be compensated. All obligatory study visits (as well as obligatory telephone calls) will be provided at no charge to subjects. Participants may reach their target FBG level more rapidly and/or with less effort. Participants may be more encouraged to perform BOT and to titrate their insulin dose. Participants may reduce their HbA1c, FBG, number of diabetic ketoacidosis (a serious complication of diabetes) or hypoglycemic (low blood sugar) events, and distress with diabetes. Participants may need less help from their physician or diabetes nurse. Participants may gain additional attention from their physician. Participants may be motivated to learn more about diabetes and to have better discussions of potential issues with their health care providers. Participants may gain personal satisfaction from participating in this study.

Where is the study run from?
Roche Diabetes Care GmbH (Germany)

When is the study starting and how long is it expected to run for?
August 2019 to February 2022

Who is funding the study?
Roche Diabetes Care GmbH (Germany)

Who is the main contact?
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Additional identifiers

Protocol serial number
DC000058, CIV-20-01-031566

Study information

Scientific Title
Efficacy of a text messaging service for patients with type 2 diabetes to support basal insulin titration

Acronym
GetFit

Study objectives
The study rationale is to analyze the efficacy of the GetFit supported titration of once-daily long-acting (basal) insulin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/04/2020, Ethik-Kommission bei der Landesärztekammer Baden-Württemberg (Liebknechtstr. 33, Stuttgart, Baden-Württemberg, 70565, Germany; +49 (0)711 7698919; ethikkommission@laek-bw.de), ref: 00012377

Primary study design
Interventional

Study design
Prospective multicenter one-arm interventional study

Study type(s)
Treatment

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

Interventions
Routine BOT therapy supported by a text messaging service: Patient needs to respond to SMS from the messaging service. In particular, the patient needs to enter Fasting Blood Glucose in the morning and the injected insulin amount in the evening (16 weeks)
Blood collection for determination of HbA1c: twice during the study (baseline and Visit 4 after 16 weeks)
Questionnaires: Patients are asked to complete electronic questionnaires (baseline and Visit 4 after 16 weeks)

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
The percentage of subjects with FBG stable in their individual target range after completion of GetFit supported basal insulin titration at latest, measured using [method] calculated using system data at Visit 4 (week 16 [±14 days])

Key secondary outcome(s)
Current secondary outcome measures as of 26/03/2021:
1. Number of days until the FBG target range was reached, calculated using system data, timepoint individual for each patient
2. Change in HbA1c measured using blood sample analysis at Visit 4 compared to baseline (pre-post)
3. HbA1c measured using blood sample analysis at visit 4
4. Change in FBG (blood glucose self-measurement) at Visit 4 compared to baseline (pre-post)
5. Total daily basal insulin dose at Visit 4, calculated using system data at timepoint individual for each patient
6. Number of hypoglycemic events, i.e., self-monitored BG < 70 mg/dl (3.9 mmol/l) from baseline to visit 4
7. Number of additional contacts (visits and telephone) between subject and HCP and other study staff concerning the use of GetFit and the insulin titration including FBG measurement and insulin administration, calculated from baseline to Visit 4
8. Adherence to the requests of the GetFit service:
8.1. Response rate to the GetFit service, specified by percent of SMS answered by the subject within the expected time between baseline and Visit 4
8.2. Response time from receiving the SMS from the GetFit service to the SMS sent by the subject between baseline and Visit 4
9. Correctness of FBG values entered into the SMS compared to the values stored in the BG meter, measured using system and BG meter data from baseline to Visit 4
10. Compliance with the advised insulin doses calculated using system data from baseline to Visit 4
11. Change in diabetes distress measured using Diabetes Distress Scale (DDS) at Visit 4

compared to baseline (pre-post)
12. Change in anxiety and depression measured using Hospital Anxiety and Depression Scale (HADS) at Visit 4 compared to baseline (pre-post)
13. Change in diabetes medication related-topics such as convenience measured using Diabetes Medication System Rating Questionnaire (DMSRQ) at Visit 4 compared to baseline (pre-post)
14. Change in social functioning measured using SF-12 at Visit 4 compared to baseline (pre-post)
15. Subject satisfaction regarding the use of the GetFit service measured using questionnaire at Visit 4 compared to baseline (pre-post)
16. HCP satisfaction regarding the use of the GetFit service measured using questionnaire at Visit 4

Previous secondary outcome measures:
1. Number of days until the FBG target range was reached, calculated using system data, timepoint individual for each patient
2. Change in HbA1c measured using blood sample analysis at Visit 4 compared to baseline (pre-post)
3. HbA1c measured using blood sample analysis at visit 4
4. Change in FBG (blood glucose self-measurement) at Visit 4 compared to baseline (pre-post)
5. Daily basal insulin dose required after reaching the FBG target range, calculated using system data, timepoint individual for each patient
6. Number of hypoglycemic events, i.e., self-monitored BG < 70 mg/dl (3.9 mmol/l) from baseline to visit 4
7. Number of additional contacts (visits and telephone) between subject and HCP and other study staff concerning the use of GetFit and the insulin titration including FBG measurement and insulin administration, calculated from baseline to Visit 4
8. Adherence to the requests of the GetFit service:
8.1. Response rate to the GetFit service, specified by percent of SMS answered by the subject within the expected time between baseline and Visit 4
8.2. Response time from receiving the SMS from the GetFit service to the SMS sent by the subject between baseline and Visit 4
9. Correctness of FBG values entered into the SMS compared to the values stored in the BG meter, measured using system and BG meter data from baseline to Visit 4
10. Change in diabetes distress measured using Diabetes Distress Scale (DDS) at Visit 4 compared to baseline (pre-post)
11. Change in anxiety and depression measured using Hospital Anxiety and Depression Scale (HADS) at Visit 4 compared to baseline (pre-post)
12. Change in diabetes medication related-topics such as convenience measured using Diabetes Medication System Rating Questionnaire (DMSRQ) at Visit 4 compared to baseline (pre-post)
13. Change in social functioning measured using SF-12 at Visit 4 compared to baseline (pre-post)
14. Subject satisfaction regarding the use of the GetFit service measured using questionnaire at Visit 4 compared to baseline (pre-post)
15. HCP satisfaction regarding the use of the GetFit service measured using questionnaire at Visit 4

Completion date
23/02/2022

Eligibility

Key inclusion criteria

1. Signed written informed consent
2. Male and female patients with at least 21 years of age
3. Diabetes mellitus type 2
4. Initiation of BOT planned including training in diabetes mellitus, BOT therapy, FBG measurement and basal insulin administration
5. Individual FBG target range set to 140 mg/dL (7.8 mmol/l) or lower by the investigator as described by BOT guidelines
6. HbA1c ≥7.5% (58,5 mmol/mol), determined within the previous 3 months
7. Possessing and using a mobile phone including SMS messaging and having access to the mobile phone network while at home (self-assessed)
8. Ability and willingness to participate in the study, to read and understand all study materials (subject information, informed consent and data protection form, IFU, SMS text messages, questionnaires) and to comply with study procedures, including daily BG measurement with the Accu-Chek® BG meter handed out for the study and administration of once-daily, long-acting insulin as well as timely sending and receiving SMS text messages in the morning and in the evening and blood draws for repeated HbA1c determination

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Prior insulin therapy except for gestational diabetes or for < 1 week
2. Current insulin therapy, e.g. prandial insulin, premixed insulin
3. Known impaired awareness of hypoglycemia with current history of regular hypoglycemia or hospitalization(s) because of severe hypoglycemia in the previous 3 months
4. Significant manifestation of severe diabetes-related long-term complications e.g. severe retinopathy, neuropathy, nephropathy requiring dialysis
5. Pregnant or planning to become pregnant or breastfeeding
6. Legal incompetence or limited legal competence
7. Serious or unstable chronic physical or psychological condition rendering the subject unable to understand the nature and the scope of the study and to follow the study procedures
8. Addiction to alcohol or other substance(s) of abuse as assessed by the investigator
9. Dependency on sponsor or Investigator (e.g. co-worker or family member)

Date of first enrolment
07/08/2020

Date of final enrolment

30/11/2021

Locations

Countries of recruitment
Germany

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Sponsor information

Organisation
Roche Diabetes Care GmbH

Funder(s)

Funder type
Industry

Funder Name
Roche Diabetes Care GmbH

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available electronic Trial Master File (Veeva Vault) according to all applicable national regulations as outlined in the most current study protocol. Datasets might be made available upon request.

IPD sharing plan summary

Stored in non-publicly available repository