Efficacy and Safety of Premixed Insulin Treatment in Patients With Type 2 Diabetes Mellitus

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Sponsor:

Nanjing First Hospital, Nanjing Medical University

Collaborators:

Wuxi Hospital of Traditional Chinese Medicine

Wuxi People's Hospital Affiliated to Nanjing Medical University

Huai'an Second People's Hospital and the Affiliated Huai'an Hospital of Xuzhou Medical University

The Affiliated Suqian First People's Hospital of Nanjing Medical University

Information provided by (Responsible Party):

Nanjing First Hospital, Nanjing Medical University

Study Description

Brief Summary:

The aim of the study is to investigate the efficacy and safety of premixed insulin treatment in patients With type 2 diabetes mellitus using professional and personal Flash Glucose Mornitoring

Detailed Description:

Professional and personal Flash Glucose Mornitoring will be used in patients with type 2 diabetes who are treated with premixed insulin. The frequency of hypogycemia and the blood glucose control will be analyzed

by flash glucose mornitoring once a month for 3 months and doctors will adjust the hypoglycemia treatment according to the results every month. HbA1c, glycemic variation, beta-cell function and **androgen levels** will be measured.

Study Design

Study Type: Interventional (Clinical Trial)

Actual Enrollment: 239 participants

Allocation: Randomized

Intervention Mode: Parallel Assignment

Masking: Double (Investigator, Outcomes Assessor)

Primary Purpose: Treatment

Official Title: Efficacy and Safety of Premixed Insulin Treatment in Patients with Type 2 Diabetes Mellitus Observed by Different Type of Flash Glucose Mornitoring

Actual Study Start Date: October 9, 2019

Actual Study Completion Date: April 30, 2021

Arms and Interventions:

Arms:

Placebo Comparator: Professional flash glucose mornitoring

Professional flash glucose mornitoring will be used in patients once a month for 3 months to monitor glucose level. Patients can learn their blood glucose levels via capillary blood glucose tests, but nor FGM duing FGM, and doctors will adjust their anti-diabetic therapy according to their FGM results after each monitoring.

Active Comparator: Personal flash glucose mornitoring

Personal flash glucose mornitoring will be used in patients once a month for 3 months to monitor glucose level. Patients can learn their blood glucose levels via FGM duing FGM, and doctors will adjust their anti-diabetic therapy according to their FGM results after each monitoring.

Interventions:

Device: Professional flash glucose mornitoring

Subjects will use Professional flash glucose mornitoring once a month for 3 months.

Device: Personal flash glucose mornitoring

Subjects will use Personal flash glucose mornitoring once a month for 3 months.

Outcome Measures

Primary Outcome Measures:

1. Time in range (Time Frame: baseline and after 3 month)

   change of Time in range

Secondary Outcome Measures:

1. HbA1c (Time Frame: after 3 month)
2. antibody of insulin (Time Frame: baseline and after 3 month)
3. angrogen levels (Time Frame: baseline and after 3 month)
4. exercise time daily (Time Frame: baseline and after 3 month)
5. meal times (Time Frame: baseline and after 3 month)
6. calorie intake (Time Frame: baseline and after 3 month)

Eligibility Criteria

Inclusion Criteria:

1. participate voluntarily and sign the subject informed consent before the test.
2. for patients with type 2 diabetes who met WHO1999 diagnostic criteria, subcutaneous injection with premix insulin Bid/Tid, single drug and/or combination of oral hypoglycemic drugs, the treatment regimen was stable for more than 2 months.
3. no acute complications such as diabetic ketoacidosis and diabetic hyperosmolar syndrome.

4. subjects are able and willing to undergo FGM examination, diet and exercise regularly.

Exclusion Criteria:

1. patients treated with GLP-1 agonist in the last 3 months
2. patients who are allergic to insulin.
3. impaired liver and renal function, ALT 2.5 times higher than the upper limit of normal value;Serum creatinine was 1.3 times higher than the upper limit of normal.
4. a history of drug abuse and alcohol dependence within the past 5 years.
5. used systemic hormone therapy in recent 3 months.
6. patients with poor compliance and irregular diet and exercise.
7. patients with infection and stress within four weeks.
8. patients who cannot tolerate flash glucose mornitoring.
9. patients who are pregnant, nursing or or preparing to become pregnant.
10. any other apparent condition or comorption as determined by the investigator, such as severe heart and lung disease, endocrine disease, neurological disease, tumor disease, other pancreatic disease, history of mental illness.

Contacts and Locations

Locations

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Investigators

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