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Effect of premixed insulin combined with mulberry twig alkaloids tablet or metformin on blood glucose fluctuation in type 2 diabetes

Submission date
13/01/2023

Recruitment status
No longer recruiting

Registration date
04/03/2023

Overall study status
Completed

Last Edited
01/12/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In recent years, more and more studies have supported the relationship between blood glucose fluctuation and macrovascular and microvascular complications. In this study, continuous glucose monitoring (CGM) was used to evaluate the effect of premixed insulin, mulberry twig alkaloids combined with premixed insulin and metformin combined with premixed insulin on blood glucose levels in patients with type 2 diabetes (T2DM). The methods will take into account changes in blood lipids, which will provide evidence for expanding and improving the clinical application of mulberry twig alkaloids.

Who can participate?
Patients with type 2 diabetes aged between 18 and 70 years old with poor blood glucose control

What does the study involve?
Patients are randomly divided into three groups comprising a premixed insulin group, premixed insulin combined with mulberry twig alkaloids group and premixed insulin combined with metformin group. Treatment will last for 6 weeks.

What are the possible benefits and risks of participating?
It is expected that the participants receiving mulberry twig alkaloids will effectively improve blood glucose fluctuation and their quality of life. Data from this study will provide evidence for expanding the clinical application of mulberry twig alkaloids. Participants may suffer side effects from the examination and the drugs used (for example, gastrointestinal adverse effects, and hypoglycemia).

Where is the study run from?
The First Affiliated Hospital of Harbin Medical University (China)

When is the study starting and how long is it expected to run for?
January 2022 to July 2023

Who is funding the study?
The First Affiliated Hospital of Harbin Medical University (China)

Who is the main contact?
Dr Hongyu Kuang, ydykuanghongyu@126.com (China)

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effect of premixed insulin combined with mulberry twig alkaloids tablet or metformin on blood glucose fluctuation in type 2 diabetes: a randomized, open-label, parallel-group, controlled clinical trial

Study objectives
Patients with type 2 diabetes were treated with premixed insulin, premixed insulin combined with mulberry twig alkaloids (Sangzhi alkaloids, SZ-A), and premixed insulin combined with metformin for 6 weeks. All three groups can effectively reduce blood glucose, but the premixed insulin combined with SZ-A may better improve the postprandial blood glucose fluctuation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/07/2022, Ethics Committee of First Affiliated Hospital of Harbin Medical University (No. 23 Postal Street, Nangang District, Harbin City, Heilongjiang Province, China; +86 (0)451-85552350; black9090@163.com) ref: 202274

Study design
Randomized open-label parallel-group controlled study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Type 2 diabetes patients with poor blood glucose control

Interventions
The participants are randomized 1:1:1 into three groups. The random number sequence is generated using the PROC PLAN command in SAS 9.4 (SAS Institute, Cary, NC, USA) and enclosed in opaque anonymous envelopes.

1. Premixed insulin combined with mulberry twig alkaloids group: mulberry twig alkaloids (Beijing Wuhe Boao Pharmaceutical Co., Ltd, Beijing, China, 50mg, dosage 4 weeks later,100mg) three times a day combined with mixed protamine zinc recombinant human insulin lispro injection (50R) (Lilly France) two times a day for 6 weeks
2. Premixed insulin combined with metformin group: metformin (500mg) three times a day combined with mixed protamine zinc recombinant human insulin lispro injection (50R) (Lilly France) two times a day for 6 weeks
3. Premixed insulin group: mixed protamine zinc recombinant human insulin lispro injection (50R) (Lilly France) two times a day for 6 weeks

The first four weeks of the treatment phase is the insulin dose titration period. The patient is required to monitor their blood glucose level by themselves. The doctor adjusts the insulin dose according to the results. The following two weeks are the steady-state dose period.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Premixed insulin (mixed protamine zinc recombinant human insulin lispro injection (50R), metformin, mulberry twig alkaloids

Primary outcome measure
Blood glucose levels measured using continuous glucose monitoring (CGM) to detect changes in blood glucose fluctuation at baseline and after 6 weeks of treatment

Secondary outcome measures
1. Fasting, 1 hour postprandial and 2 hours postprandial blood glucose levels, blood glucagon-like peptide 1 (GLP-1) levels, inflammatory factors (C-reactive protein (CRP), IL-6, etc.), oxidative stress (MDA, SOD, etc.), and blood lipid parameters measured in venous blood using standard methods at baseline and 6 weeks
2. Glycosylated hemoglobin and glycosylated albumin measured in venous blood using standard methods at baseline and 6 weeks
3. Treatment satisfaction measured using the Diabetes Treatment Satisfaction Questionnaire

(DTSQ) at baseline and 6 weeks
4. Quality of life measured using the Chinese Normal Audit of Diabetes-Dependent Quality of Life (CN-ADDQoL) at baseline and 6 weeks

Overall study start date
01/01/2022

Completion date
20/07/2023

Eligibility

Key inclusion criteria
1. Aged between 18 and 70 years old, regardless of gender
2. Body mass index (BMI) between 19 and 30kg/m2
3. Diagnosed as type 2 diabetes according to the diagnostic criteria for type 2 diabetes formulated by the 1999 World Health Organization
4. Type 2 diabetes patients with poor blood glucose control 7% ≤ HbA1c ≤ 10%
5. Able to understand the procedures and methods of this clinical study, participate voluntarily and sign the informed consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Ineffective, allergy or intolerance to α-glucosidase inhibitors
2. Severe diabetic complications
3. Secondary diabetes mellitus, specific types of diabetes, type 1 diabetes
4. Chronic gastrointestinal dysfunction, obvious digestive and absorption disorders, as well as other endocrine diseases, such as hyperthyroidism, Cushing syndrome, acromegaly, etc
5. Patients with diseases that may worsen due to flatulence (such as Roeheld syndrome, severe hernia, intestinal obstruction, after gastrointestinal surgery and intestinal ulcer)
6. Unstable angina pectoris within half a year, have serious heart diseases and are likely to die in the treatment and follow-up period
7. People with mental and neurological disorders who cannot correctly express their will

8. Alcoholics, drug abusers and addicts
9. Women of childbearing age who are pregnant, lactating, intending to be pregnant or positive in a pregnancy test (urine HCG or blood HCG), and cannot take effective contraceptive measures during the test (effective contraceptive measures include sterilization, intrauterine device, oral contraceptives etc
10. Those who have participated in clinical trials of other drugs or medical devices in the past three months

Date of first enrolment
20/07/2022

Date of final enrolment
01/06/2023

Locations

Countries of recruitment
China

Study participating centre
The First Affiliated Hospital of Harbin Medical University
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Organisation
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Sponsor type
Hospital/treatment centre

Website

http://www.54dr.com/

ROR
https://ror.org/05vy2sc54

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
First Affiliated Hospital of Harbin Medical University

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/09/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the principle of informed consent which indicated that the patient's personal data will not be public.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/11/2023	01/12/2023	Yes	No