Informed Consent Form

Dear fellow patients,

Your current disease is obesity, and we invite you to participate in a clinical study. Participating in this study is entirely your choice. This informed consent will provide you with some information, please read carefully, and carefully make the decision whether to participate in the study. If you have any questions about this study, you can ask your doctor or the researcher for an explanation. You can discuss this with family and friends to help you decide whether to volunteer for this clinical study. You have the right to refuse to participate in the study or to withdraw from the study at any time without penalty or loss of your rights. If you agree to participate, we will require you to sign and date this Informed Consent form. You will be provided with a signed and dated copy for you to keep.

Your participation in this study is voluntary, and this study has been reviewed by the Medical Ethics Committee of our hospital.

[Study name] diet intervention of obesity-related complication

Researcher: ShenQu Department: Endocrinology

Version number: 1.0 Version Date: June 23, 2024

Why was this study conducted?

With the reform and opening up and the progress of China's economic power, people's eating habits have developed in the direction of high salt, sugar, fat and calories, resulting in a surge in food-borne diseases, and obesity has become one of the major killers of national health and a major global public health challenge.

Obesity-related complications, including diabetes, Metabolic associated Fatty Liver Disease (MAFLD), hyperlipidemia and other metabolic diseases listed in the Clinical Practice Guidelines for the Integrated Management of Obese Patients published by the American Association of Clinical Endocrinologists, And stress osteoarthritis, stress urinary incontinence, gastroesophageal reflux disease and other volume-load-related diseases [3]. Obesity is also closely associated with gastric mucosal injury diseases, such as gastric ulcer and gastric cancer. How obesity-related stomach damage is diagnosed and treated. It is of great significance to study the mechanism of obesity-related gastric mucosa injury for reducing the risk of obesity-related gastric cancer. The purpose of this study was to investigate the effect of low LA diet on obesity-related gastric injury.

How was the study conducted?

1. This clinical study was a 3-month prospective, single-center trial. Obese adults aged 18-65 years were recruited. After signing the informed consent, patients who met the inclusion/exclusion criteria were randomly assigned to the intervention group and the control group after completing baseline clinical visits and data collection. Volunteers in the intervention group ate three standard meals a day on a low-LA diet. Breakfast is from 7:00 to 9:00, lunch is from 11:00 to 13:00, and dinner is from 17:00 to 19:00. In addition to the prescribed eating activities, the patients in the intervention group were forbidden to eat other foods (water consumption was not restricted).The intervention lasted for 12 weeks. You will need to return for regular follow-up visits as scheduled by your doctor. During treatment and follow-up, the researchers will use relevant clinical observation forms to collect all the data

you need to observe. At the beginning of the study and at the 4th, 8th and 12th weeks after the start of the study, biochemical examinations will be arranged in the secretion outpatient department of **the shanghai tenth people's hospital**, and relevant questionnaires will be filled in for research analysis. Finally, data will be summarized and statistical analysis will be performed.

[Requirements for study participation]

This study plans to recruit 30 subjects.

The inclusion criteria were:

(1) Men and premenopausal women, aged 18-65 years at the time of signing the informed consent

(2) Obese patients were diagnosed based on body mass index (BMI) 28-40kg/m2

2. Exclusion criteria are:

1) Patients who do not have or lose the ability to make autonomous judgments, do not understand the purpose of the study, or are unwilling to cooperate;

2) Heart, liver, kidney dysfunction and systemic diseases, such as various malignant tumors, systemic allergic diseases, autoimmune diseases;

3) Drug or alcohol dependence, intellectual disability, mental disorders;

4) Pregnant and lactating women;

5) Confirmed Helicobacter pylori infection (PPI, bismuth and antibiotics were stopped for at least 4 weeks, and any of the following tests were positive: non-invasive Hp test such as urea breath test, monoclonal stool Helicobacter pylori antigen test, serum soluble Helicobacter pylori antigen test; Invasive Hp test included rapid urease test and tissue section staining);

6) diagnosis of acute gastric mucosal lesions;

7) According to the Consensus Opinion on Chronic Gastritis in China in 2017, the patient was diagnosed with chronic gastritis according to the new Sydney system visual simulation scoring method and the pathological diagnostic criteria of chronic gastritis in China;

8) Patients with gastroscopy and histological pathology who meet the diagnostic criteria for gastric ulcer

9) the Diagnosis and Treatment of Gastric Cancer, combined with endoscopic, histological and imaging examinations, adenocarcinoma was diagnosed

The exit criteria are:

You may request the termination of the clinical study at any time without giving any reason. If at any time you or the investigator decide that it is not in your best interest to continue the study, or if you are unable to continue to participate in the study, the Investigator may withdraw you from the study at any time that the Investigator determines is in your best interest. Researchers, ethics committees and health authorities may stop the study at any time without your consent, but will explain the reasons for stopping the study. If your initial study is stopped, you will be asked to undergo a routine examination and, if possible, follow up with you until the end of the study.

You may withdraw or end this study early for any of the following reasons

The subject requests withdrawal of informed consent

Inclusion in trials that violated inclusion and/or exclusion criteria and/or randomization criteria

Safety concerns are at the discretion of the investigators

Subjects will not tolerate serious adverse events

Excessive alcohol consumption (>70 g/wk) and smoking habits

Diagnosed with cancer, kidney disease or diabetes, lactose intolerance

Suspected pancreatitis

Pregnant or trying to get pregnant

To participate in a clinical trial of another approved or unapproved investigational drug product

How long will I participate in this study?

Your participation in the study will last for 12 weeks, during which you will be required to make 5 visits to the department. The study consisted of the following components: screening period, baseline period, intervention period (week 4, week 8), and endpoint period. Follow-up refers to the collection of your recent medical history and adverse reactions without affecting your normal medical treatment. Each follow-up visit takes half a day.

What are my responsibilities?

If you decide to participate in the study, you must come to the hospital at the time of follow-up agreed upon by your doctor and you. Your follow-up is very important because your doctor will judge whether the treatment you receive is really working and guide you in time.

As a subject, you will need to provide truthful information about your medical history and current physical condition; Eat according to the doctor's guidance, avoid overeating, cooperate with the doctor's work, avoid extra food intake; You are also asked to take timely and objective measurements using the scales and scales provided in the study and to fill out your treatment records. Truthfully tell the researcher of any discomfort found during this study, and cannot participate in other drug or diet-related clinical studies during the study.

What will each research visit do?

Screening period: Understand the purpose and content of the study, screen according to the inclusion criteria, and sign the informed consent

Baseline period: Basic information was asked, physical examination and in boday were performed, biochemical and imaging examinations were performed, 24-hour diet review scale was performed, and gastric tissue samples were taken to evaluate gastric injury indicators

Week 4: Biochemical examination was scheduled 3 days in advance, and physical examination and in boday were conducted at the follow-up time of week 4

Week 8: Biochemical examination was scheduled 3 days in advance, and physical examination and in boday were performed at the follow-up time of week 8

End stage: Final physical examination and in boday, biochemical and imaging examinations, gastric tissue samples to assess gastric injury, assessment of participants' effects, and scientific treatment plan for patients.

What are the possible risks for me in this study?

Venous blood collection is a common clinical operation, and there are no obvious complications in regular hospitals. If the following risks occur

You should discuss these risks with your researcher.

During the study period, you may experience some, all or none of these adverse events (adverse medical events occurring during or after the subject's blood collection), risks, discomfort, inconvenience, such as:

(1) Subcutaneous bleeding or local hematoma at or around the blood collection site may cause pain, swelling or ecchymosis
(2) A small number of dizzy needles and blood, in the process of venous blood collection, may cause dizziness, heart palpitations, doctor loss and other adverse symptoms
(3) Blood collection failed and there was no obvious blood return after puncture, indicating that venipuncture was caused by inaccuracy
(4) Cause local allergic reactions to the skin, mostly in patients with a history of allergy, local manifestations of rash or allergic dermatitis
Other risks: There may also be risks, discomfort or adverse reactions that are not currently foreseen.

What are the possible benefits of participating in this study?

You will benefit from this study for three months, the diet intervention and guidance of specialized doctors, professional endocrinologists to interpret your indicators and life guidance, to help you develop a good lifestyle. Dietitians conduct weekly healthy eating related training, responsible for solving your dietary doubts, and help you achieve the desired weight loss through professional knowledge. A dedicated phototherapist is responsible for supervision and care to help you improve compliance throughout the study. In this study, you will receive careful assessment, monitoring and dietary treatment in addition to routine monitoring. Your weight loss, fatty liver, hypertension, hyperlipidemia, prediabetes and other complications caused by obesity may be improved. Good living habits will make you mentally healthy, and at the same time provide useful information for the research of obesity-related gastric injury diseases.
We hope that the information gained from your participation in this study will benefit you or other patients with your condition in the future.
What treatment options do I have if I don't participate in the study?
Other alternative treatments or therapies that may be available to the subject, and their associated benefits and risks.

What happens to my personal information?

During the study, we will collect information about your medical history, laboratory and imaging results, and follow-up information. To ensure privacy, we will encode some of your information. Your personal identifier (e.g. name, date of birth, address) will be replaced by a code (unique patient number) so that no one can determine your identity. Except for this study, your information will not be used again in the future.
With the understanding and assistance of you and the other subjects, the results of this study may be published in a medical journal, but we will keep your study records confidential and will not disclose your identity as required by law. The personal information of research subjects will be kept strictly confidential, and your personal information will not be disclosed unless required by relevant law. If necessary, government authorities and hospital ethics committees and other relevant researchers may access your data as required.

Who can I contact to learn more about this study?

If you have any questions related to this study, please contact Dr. Bule at 021-66301004 during working hours, +8617701621016 or +8613651608412 after hours, on weekends and holidays.

Informed consent

Signature page

I have been informed of the purpose, background, process, risks and benefits of the study, and I have read this informed consent document and understood the procedure, treatment and purpose of the study, as well as the possible benefits and risks of participating in the study. This consent form is written in a language I am fluent in, I have had the opportunity to ask questions, and all my questions have been answered in a way I can understand.

I agree that the research doctor collects and processes information about me, including information about my health, and I agree that the information about me will be made available to the research doctor for scientific research.

I will comply with the study doctor's advice regarding the conduct of the study, but I am aware that I have the right to withdraw my voluntary consent to participate in the study at any time without losing the benefit of further medical care.

I understand that by signing this Consent form I do not waive any legal rights.

I will receive a copy after signing this consent form and the original will be retained in the archives of the Research Center.

Subject Signature: Date:

(Note: If the subject is incapacitated/has limited capacity, signature and signature date of legal representative are required)

Signature of Legal Representative: Date:

(Note: If the subject is unable to read the informed consent, a fair witness is required to certify that the investigator has informed the subject of all contents of the informed consent, and the fair witness is required to sign and sign the date)

Fair Witness Signature: Date:

Investigator Signature: Date: