ISRCTN47827392 https://doi.org/10.1186/ISRCTN47827392

Construction of the "undiseased" status bank for type 2 diabetes mellitus complicated with osteoporosis

Submission date
15/06/2024

Recruitment status
Recruiting

Registration date
19/06/2024

Overall study status
Ongoing

Last Edited
04/08/2025

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus combined with osteoporosis (T2DM-OP) has a high prevalence rate and high disability/death rate, and the bone mass level of patients is an important marker of the evolution and development of this disease. Early identification of the stage of T2DM-bone loss is an important strategy to prevent T2DM-OP. The study aims to screen the identifiable and quantifiable clinical phenotypes and key molecules of the "undiseased" state of T2DM-OP, and construct a mathematical model reflecting the critical transition of "the undiseased" in T2DM-OP to reveal the internal change leading to the occurrence and development of the disease.

Who can participate?
Patients aged 45 to 80 years old with type 2 diabetes mellitus

What does the study involve?
Patients with type 2 diabetes will be recruited and divided into three levels of normal bone mass, bone loss and osteoporosis through DEXA bone density detection, and clinical information and biological samples will be collected, including: general demographic information (gender, age, menopause, diet, lifestyle and other general social demographic information, as well as personal history, past history, family history, height, weight and other background information); complications and main drug use; number of fractures; traditional Chinese medicine (TCM) syndrome judgment; grip strength and sitting and standing test time; bone density (lumbar spine and hip bone density) and skeletal muscle mass. 10 ml blood will be collected from participants fasting in the morning to detect bone, glucose and lipid metabolism related markers and cytokines.

What are the possible benefits and risks of participating?
Participants may benefit from this study, including better assessment and monitoring of blood glucose and bone mass to inform clinical decision-making. They can also get reasonable and standardized clinical decision-making advice and improve their quality of life.

The study was an observational study and participants underwent routine medical practices with risks similar to those of a daily physical examination, so it did not pose any risks outside of routine medical treatment.

Where is the study run from?
Wangjing Hospital of China Academy of Chinese Medical Sciences (China)

When is the study starting and how long is it expected to run for?
January 2024 to December 2026

Who is funding the study?
National Natural Science Foundation of China (T2341023) (China)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NSFC-T2341023

Study information

Scientific Title
Study on "undiseased" status characterization and critical warning mechanism of type 2 diabetes mellitus complicated with osteoporosis

Acronym
DECODE-TOP

Study objectives
1. To screen the identifiable and quantifiable clinical phenotypes and key molecules of the "undiseased" state of type 2 diabetes mellitus combined with osteoporosis.
2. To construct a mathematical model reflecting the critical transition of the "undiseased" in type 2 diabetes mellitus combined with osteoporosis, and reveal the internal change law leading to the occurrence and development of the disease.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/05/2024, Medical Ethics Committee of Wangjing Hospital, China Academy of Chinese Medical Sciences (No.6 South Zhonghuan Road, Chaoyang District, Beijing, 100102, China; +86 (0)10-84739223; wjyyec@126.com), ref: WJEC-KT-2024-035-P001

Study design
Observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Community, Hospital

Study type(s)
Prevention, Screening

Participant information sheet
Not applicable

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

Interventions
Patients with type 2 diabetes will be recruited and divided into three levels of normal bone mass, bone loss and osteoporosis through DEXA bone density detection, and clinical information and biological samples will be collected, mainly including:
1. General demographic information (gender, age, menopause, diet, lifestyle and other general social demographic information, as well as personal history, past history, family history, height, weight and other background information)
2. Complications and main drug use
3. The number of fractures
4. TCM syndrome judgment
5. Grip strength and 5 times sitting and standing test time
6. Bone density (focus on monitoring lumbar spine and hip bone density) and skeletal muscle mass
7. 10 ml venous blood will be collected from the subjects in the fasting state in the morning to detect bone metabolism indexes, glucose metabolism related indexes, lipid metabolism related indexes, and cytokines.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 04/08/2025:
Bone density (focus on monitoring lumbar spine and hip) and body composition analysis measured using dual-energy X-ray absorptiometry (DXA) at baseline

Previous primary outcome measure:
Bone density (focus on monitoring lumbar spine and hip) measured using dual-energy X-ray absorptiometry (DXA) at baseline

Secondary outcome measures
1. General demographic information is measured using a questionnaire at baseline, including gender, age, menopause, diet, lifestyle and other general social demographic information, as well as personal history, past history, family history, height, weight and other background information
2. Complications and main drug use measured using a questionnaire by way of inquiry at baseline
3. The number of fractures is measured using a questionnaire by way of inquiry at baseline
4. Traditional Chinese medicine (TCM) syndrome judgment is judged by professional traditional Chinese medicine doctors at baseline
5. Grip strength measured using dynamograph at baseline

6. The five-times-sit-to-stand test measured using timer at baseline
7. Skeletal muscle mass measured using dual-energy X-ray absorptiometry (DXA) at baseline
8. Laboratory tests (blood) using ELISA at baseline. 10 ml venous blood will be collected from the subjects in the fasting state in the morning to detect bone metabolism indexes, glucose metabolism related indexes, lipid metabolism related indexes, and cytokines.

Overall study start date
01/01/2024

Completion date
30/12/2026

Eligibility

Key inclusion criteria
1. Meet the diagnostic criteria for type 2 diabetes mellitus
2. Aged 45 to 80 years old, male or female
3. Signed the informed consent, and the respondents voluntarily participated in the survey

Participant type(s)
Patient

Age group
Adult

Lower age limit
45 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
1000

Key exclusion criteria
1. Type 1 diabetes mellitus and specific type diabetes mellitus
2. Patients with severe cardiovascular diseases, liver and kidney diseases, malignant tumors and other wasting diseases and infectious diseases
3. Patients with mental disorders such as Alzheimer's disease, mental illness or depression, or who are unable to cooperate with the completion of the trial
4. Patients with acute metabolic disorders such as diabetic ketoacidosis in the past 1 month
5. Patients with other diseases of the endocrine system, such as Cushing's syndrome, hyperthyroidism, hypothyroidism, etc
6. Patients taking oral or intravenous glucocorticoids, oral estrogen and progesterone replacement therapy
7. Those who are participating in other clinical trials

Date of first enrolment
17/10/2024

Date of final enrolment
01/07/2026

Locations

Countries of recruitment
China

Study participating centre
Wangjing Hospital, China Academy of Chinese Medical Sciences
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100102

Study participating centre
Zhengda Shaoyang Orthopaedic Hospital
16, Dongxi Road
Niangxi Town
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Shaoyang City
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Study participating centre
Nanyang Orthopaedic Hospital
88, Gongye South Road
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338, Huanghe Avenue
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Sponsor type
Government

Website
http://www.nsfc.gov.cn/publish/portal1/

ROR
https://ror.org/01h0zpd94

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Alternative Name(s)

Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Publication and dissemination plan
1. The study protocol will be submitted to a peer-reviewed journal
2. The results will be submitted to a peer-reviewed journal

Intention to publish date
01/06/2027

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date