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Effectiveness and safety of Qiming granules in the treatment of nerve injury in non-proliferative diabetic retinopathy

Submission date
30/08/2022

Recruitment status
No longer recruiting

Registration date
01/09/2022

Overall study status
Completed

Last Edited
19/05/2025

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
Diabetic retinopathy (DR) is a complication of diabetes caused by high blood sugar levels damaging the back of the eye (retina). It is usually diagnosed and treated at a late stage when blood vessel changes occur, leading to poor effectiveness. Therefore, a new concept of DR treatment, which is targeted at nerve injury, needs to be established. This study aims to assess the effectiveness and safety of Qiming granules as an early intervention for nerve injury associated with non-proliferative DR (NPDR) (without abnormal blood vessel growth).

Who can participate?
Patients with type 2 diabetes mellitus, NPDR, and/or DR-associated nerve injury without fundus abnormalities (the part of the eyeball opposite the pupil)

What does the study involve?
Participants are randomly allocated to receive Qiming granule or calcium dobesilate (CaD) for 24 weeks. Retinal nerve fiber layer thickness and foveal avascular zone area are measured before and after 24 weeks of treatment.

What are the possible benefits and risks of participating?
It is expected that the participants receiving Qiming granules can effectively control diabetes retinopathy and improve their quality of life. The important information obtained in this study may provide a theoretical basis for retinal nerve injury in patients and help to increase their own or other patients' treatment options. During visits 1, 2 and 3, participants could obtain a transportation fee of 200 RMB per person per time. Participants may suffer side effects from the examination and drugs (for example, gastrointestinal adverse effects).

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

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

Who is funding the study?
Beijing Bethune Charitable Foundation (China)

Who is the main contact?
Prof. Hongyu Kuang, ydykuanghongyu@126.com

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Efficacy and safety of Qiming granules for nerve injury associated with non-proliferative diabetic retinopathy: a multicenter, randomized, non-inferiority, active-controlled clinical trial

Study objectives
Type 2 diabetic patients with non-proliferative diabetic retinopathy and/or nerve injury without fundus abnormalities were treated with Qiming granules and calcium dobesilate capsules for 24 weeks, respectively. Retinal neuroprotective effect and fundus improvement in the Qiming granule group are not inferior to that in the calcium dobesilate capsule group.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 20/12/2019, Ethics Committee of Frist 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: 2019152

Study design
Multicenter randomized non-inferiority active-controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes with non-proliferative diabetic retinopathy and/or nerve injury without fundus abnormalities

Interventions
The participants are randomized 1:1 into two 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.

The participants in the Qiming granule group receive Qiming granules (Zhejiang Wansheng Pharmaceutical Co., Ltd., Hangzhou, China, 4.5 g) mixed with boiling water three times a day for 24 weeks. The participants in the control group receive calcium dobesilate capsules (Ebewe Pharma GmbH, Unterach am Attersee, Austria, 0.5 g) three times a day for 24 weeks.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Qiming granule, calcium dobesilate

Primary outcome(s)
Retinal nerve fiber layer (RNFL) thickness and foveal avascular zone (FAZ) area measured using optical coherence tomography angiography (OCTA) at baseline and 24 weeks

Key secondary outcome(s))
1. Retinal nerve fiber layer (RNFL) thickness and foveal avascular zone (FAZ) area are measured using the optical coherence tomography angiography (OCTA) at baseline and 12 weeks
2. The proportion of abnormal full-field electroretinogram (ERG) results measured using full-field ERG at baseline, 12 and 24 weeks
3. The proportion of abnormal dilated fundus examination results measured using fundoscopy at baseline, 12 and 24 weeks
4. The proportion of abnormal visual acuity measured using visual chart and comprehensive

optometry at baseline,12 and 24 weeks
5. Quality of life measured using the visual function questionnaire (NEI-VFQ-25), the health survey questionnaire (SF-36 scale) and the scores of traditional Chinese medicine (TCM) syndrome element scale at baseline, 12 and 24 weeks

Completion date
31/03/2022

Eligibility

Key inclusion criteria
1. Aged 18-70 years
2. Diagnosed with type 2 diabetes mellitus according to the World Health Organization (WHO) 1999 diagnostic criteria
3. Diagnosed with nonproliferative diabetic retinopathy (NPDR) according to the 2002 International Clinical Diabetic Retinopathy Disease Severity Scale
4. Nerve injury was confirmed by electroretinogram (ERG)
5. Corrected visual acuity ≥0.8
6. Received stable hypoglycemic drug therapy for ≥3 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Total final enrolment
82

Key exclusion criteria
1. Other non-diabetic ocular diseases that might interfere with the results of fundus examination (such as glaucoma, cataract, non-diabetic hemorrhagic eye disease, uveitis, retinal detachment, optic nerve disease, ocular refractive interstitial abnormalities, etc)
2. Proliferative diabetic retinopathy (PDR)
3. HbA1c >8.0%
4. Diabetic retinopathy (DR) caused by type 1 or special types of diabetes
5. Intraocular surgery within 6 months, 6) central nervous system diseases
7. Allergic diseases or allergic to the study drugs

8. Participated in clinical trials within the past 3 months
9. Used drugs for the treatment of DR within the past 3 months
10. Severe systemic diseases, malignant tumors, mental illnesses, or others that might interfere with the results of this study
11. Could not take medicines as planned, or unwilling or unable to perform regular follow-up

Date of first enrolment
01/02/2020

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
China

Study participating centre
The First Affiliated Hospital of Harbin Medical University
No. 23 Postal Street
Nangang District
Harbin City
China
150001

Study participating centre
Cangzhou Central Hospital
No. 16, Xinhua West Road
Yunhe District
Cangzhou City
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Study participating centre
The First Affiliated Hospital of Henan University of Science and Technology
No. 24, Jinghua Road
Jianxi District
Luoyang City
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450052

Study participating centre

The Affiliated Hospital of Southwest Medical University
No. 25, Taiping Street
Jiangyang District
Luzhou City
China
646000

Sponsor information

Organisation
First Affiliated Hospital of Harbin Medical University

ROR
https://ror.org/05vy2sc54

Funder(s)

Funder type
Charity

Funder Name
Beijing Bethune Charitable Foundation

Results and Publications

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		15/05/2025	19/05/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes