

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

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<b>Registration date</b> 01/09/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/05/2025	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

### Contact name

Dr Hongyu Kuang

### Contact details

No. 23 Postal Street  
Nangang District  
Harbin City  
Heilongjiang Province  
Harbin  
China  
150001  
+86 (0)13339300885  
ydykuanghongyu@126.com

## Additional identifiers

### Clinical Trials Information System (CTIS)

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  $\geq 0.8$
6. Received stable hypoglycemic drug therapy for  $\geq 3$  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

China

061011

**Study participating centre**

**The First Affiliated Hospital of Henan University of Science and Technology**

No. 24, Jinghua Road

Jianxi District

Luoyang City

China

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?
<a href="#">Results article</a>		15/05/2025	19/05/2025	Yes	No