

Intraocular injection conbercept is safe and effective to improve vision, relieve symptoms for patients suffered from choroidal neovascularization secondary to punctate inner choroidopathy

Submission date 08/05/2017	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 11/05/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 31/01/2019	Condition category Eye Diseases	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Punctate inner choroidopathy (PIC) is eye disease that affects the choroid (connective tissue layer of the eye) and the retina (the part of the eye where light signals are sent to the brain to create an image). It often occurs in young women and can lead to vision loss. It causes small, yellow lesions, usually at the back of the eye. Symptoms of PIC include blurred vision, photopsia (flashes of lights), and scotomata (blind spots). The majority cases of PIC are usually have good visual prognosis (outcomes). However, choroidal neovascularization (CNV) can develop secondary to PIC leading to blindness. CNV creates a layer of new blood vessels in the choroid layer of the eye which can damage vision. The treatment for CNV is to take anti-vascular endothelial growth factor medications (to control and reduce formation of new blood vessels). Conbercept has recently been approved China as a medication that can be used to treat CNV. The aim of this study is to see whether intravitreal injection (an injection into the eye) of conbercept is a safe and effective way to improve vision and anatomical outcomes in patients with CNV and PIC.

Who can participate?

Adults aged 18 and older who have CNV.

What does the study involve?

Participants receive a single injection of conbercept. If they have swelling, extra fluid or leakage found in the eyes they are re-injected with the medication. Participants attend monthly follow up appointments for six months. Participants are assessed for their vision, leakage, and fluid buildup to see if there has been any improvement to their CNV/PIC symptoms. The researchers collect this information by reviewing medical records in order to see how effective and safe this treatment is.

What are the possible benefits and risks of participating?

There are no notable benefits or risks with participating.

Where is the study run from?

Zhongshan Ophthalmic Center (China)

When is the study starting and how long is it expected to run for?

March 2015 to November 2016

Who is funding the study?

1. National Natural Science Foundation of China (China)

2. Fundamental Research Funds of State Key Laboratory of Ophthalmology (China)

Who is the main contact?

Professor Feng Wen

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

20150501

Study information

Scientific Title

Efficacy and safety of conbercept as a primary treatment for choroidal neovascularization secondary to punctate inner choroidopathy

Study objectives

The aim of this study is to see whether intravitreal injection conbercept in "PRN" regime is safe and effective to improve vision and anatomical outcomes in patients with naïve choroidal neovascularization secondary to punctate inner choroidopathy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Zhongshan Ophthalmic Center of Sun Yat-sen University Medical Ethics Board, 27/02/2015, ref: 2015MEKY020

Primary study design

Observational

Study design

Retrospective single-center consecutive interventional non-comparative case series

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Active subfoveal or juxtafoveal CNV secondary to punctate inner choroidopathy

Interventions

Participants who require treatment for CNV receive a single intravitreal injection of 0.5mg conbercept at baseline. Reinjection is given if intraretinal edema or subretinal fluid is observed with optical coherence tomography (OCT) or if leakage within the lesion is observed with fluorescein angiography (FA).

Participants are followed up with monthly visits for six months. They are assessed for their best corrected visual acuity (BCVA). Participants' anatomical features are assessed with OCT at each monthly visit, FA and indocyanine green angiography (ICGA) at baseline and six months.

The researchers collect this information by reviewing medical records in order to see how effective and safe this treatment is.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

conbercept

Primary outcome(s)

1. Visual outcomes (best-corrected visual acuity BCVA) are measured using an eye test at baseline, and month one, two, three, four, five and six
2. Anatomical outcomes (CRT, subretinal or intraretinal fluid build up) is measured manually based on patients' OCT images using a scale of Heidelberg software at baseline and month one,

two, three, four, five and six

3. Angiographic leakage is measured by fluorescein angiography (FA) images at month one, two, three, four, five and six

4. Number of treatments is measured using patient interviews at month one, two, three, four, five and six

5. Adverse events are measured using patient interviews at month one, two, three, four, five and six month

Key secondary outcome(s)

1. The change in the size of choroidal neovascularization (CNV) is measured using patients' fluorescein angiography (FA) images at baseline and month six

2. The change in number or size of punctate inner choroidopathy (PIC) lesions is measured using patients' indocyanine green angiography images at baseline and month six

Completion date

26/11/2016

Eligibility

Key inclusion criteria

1. Active subfoveal or juxtafoveal CNV secondary to PIC, where PIC was defined as multiple, small yellow-white lesions or atrophy in the posterior pole that had typical manifestations on optical coherence tomography (OCT) images

2. PIC lesions observed around the CNV. CNV was considered active if leakage within the lesion are observed with fluorescein angiography (FA) or intraretinal edema or subretinal fluid was observed with OCT

3. Adults aged 18 and older

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. CNV was secondary to other causes, such as AMD, PCV, fundus angioid streaks, or trauma

2. Presence of any other ophthalmic diseases

3. Prior treatment of CNV, including thermal laser photocoagulation, submacular surgery, intravitreal any anti-VEGF drugs, and photodynamic therapy (PDT)

4. Administration immunosuppressants or corticosteroids (local or systemic) in observation period
5. Presence of systemic diseases or pregnancy

Date of first enrolment

01/05/2015

Date of final enrolment

30/06/2016

Locations

Countries of recruitment

China

Study participating centre**Zhongshan Ophthalmic Center**

Sun Yat-sen University

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Sponsor information

Organisation

Zhongshan Ophthalmic Center

ROR

<https://ror.org/0064kty71>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

National Natural Science Foundation of China (grant number 81570831, 81470647)

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Pengyuting at pengyuting08@163.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/06/2017	31/01/2019	Yes	No