ISRCTN85678307 https://doi.org/10.1186/ISRCTN85678307

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

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
Prof Feng Wen

ORCID ID
http://orcid.org/0000-0003-3319-4051

Contact details
State Key Laboratory of Ophthalmology
Zhongshan Ophthalmic Center
Sun Yat-sen University
54 South Xianlie Road
Guangzhou
China
510060

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Universit Medical Ethics Board, 27/02/2015, ref: 2015MEKY020

Study design
Retrospective single-center consecutive interventional non-comparative case series

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Active subfoveal or juxatoveal 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 measure
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

Secondary outcome measures
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

Overall study start date
01/03/2015

Completion date
26/11/2016

Eligibility

Key inclusion criteria
1. Active subfoveal or juxatoveal 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

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
Target number of participants was 16.

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
54 South Xianlie Road
Guangzhou
China
510060

Sponsor information

Organisation
Zhongshan Ophthalmic Center

Sponsor details
State Key Laboratory of Ophthalmology
Sun Yat-sen University
54 South Xianlie Road

Guangzhou
China
510060

Sponsor type
Hospital/treatment centre

Website
http://www.zocophlab.com/

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
the Fundamental Research Funds of State Key Laboratory of Ophthalmology

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2017

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