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Intraocular injection conbercept is effective to improve vision, relieve symptoms for patients suffered from polypoidal choroidal vasculopathy

Submission date
27/05/2017

Recruitment status
No longer recruiting

Registration date
07/06/2017

Overall study status
Completed

Last Edited
06/06/2017

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Age-related macular degeneration (AMD), a painless eye condition that causes the loss of vision, is the leading cause of irreversible blindness in elderly people globally. In Asian populations, polypoidal choroidal vasculopathy (PCV) is a common subtype of exudative (fluid and swelling) AMD. PCV 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. Given the aging Asian populations, it is estimated even more people will eventually suffer from PCV. Half of all patients with PCV show recurrences and eventual visual loss indicating the urgent need for effective PCV treatments. The treatment for PNV 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 PCV. The aim of this study is to investigate whether intravitreal injection (an injection into the eye) conbercept in "3+PRN" regime (or as needed) is a safe and effective way to improve vision and anatomical outcomes in patients with PCV who have not received treatment.

Who can participate?
Adults aged 50 and older who have not been treated for PCV who received three intravitreal injections over three months.

What does the study involve?
Participants receive a series of three injections of conbercept over three months. 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 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 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?
September 2014 to August 2016

Who is funding the study?
1. The National Natural Science Foundation of China (China)
2. The Fundamental Research Funds of the State Key Laboratory of Ophthalmology (China)

Who is the main contact?
Professor Feng Wen

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
201410

Study information

Scientific Title
Short-term efficacy of intravitreal conbercept in treatment-naive patients with polypoidal choroidal vasculopathy

Study objectives
The aim of this study is to investigate whether intravitreal injection conbercept in “3+pro re nata (PRN)” regime safe and effective to improve vision and anatomical outcomes in patients with treatment-naive polypoidal choroidal vasculopathy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Zhongshan ophthalmic center of medical ethics board at the Zhongshan Ophthalmic Center of Sun Yat-sen University, 06/03/2014, ref: 2014MEKY011

Study design
Retrospective observational 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
Treatment-naive PCV characterized by the presence of polyps with or without BVN in posterior pole on indocyanine green angiogram (ICGA), with subretinal/intraretinal fluids observed on optical coherence tomography (OCT) or leakage on fluorescein angiography (FA)

Interventions
Participants with symptomatic, treatment-naive PCV, who received intravitreal conbercept injections in "3+PRN" regime at the Macula Service of Zhongshan Ophthalmic Center of Sun Yat-sen University between November 2014 and June 2016 are included in this study. 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). Some participant may have their indocyanine green angiogram (ICGA) reexamined after three continuous monthly intravitreal injections. Patient's vision, OCT, and ICGA images, the number of injections and injection related complications were analyzed.

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 regression of polyps or BVN, greatest linear dimension (GLD), total lesion area (TLA), polyp

largest diameter (PLD), and polyp lesion area (PLA) were assessed based on ICGA at baseline and the visit after three continuous injections. The total duration of the intervention and follow-up for all participants was six months.

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

Intervention Type
Other

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. Optical coherence tomography (OCT) outcomes CRT are measured manually using a scale of Heidelberg software at baseline and month one, two, three, four, five and six follow-up based on patients' OCT images, subretinal or intraretinal fluid build-up are evaluated based on OCT at first and the 6-month visit.
3. The regression of polyps or BVN, greatest linear dimension (GLD), total lesion area (TLA), polyp largest diameter (PLD), and polyp lesion area (PLA) were assessed based on ICGA at baseline and the visit after three continuous injections.
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 monthly follow-up visit

Secondary outcome measures
Polyps (whether they have breached retinal pigment epithelium (RPE)) are measured using OCT images at month one, two, three, four, five and six

Overall study start date
01/09/2014

Completion date
20/08/2016

Eligibility

Key inclusion criteria
1. Treatment-naive PCV characterized by the presence of polyps with or without BVN in posterior pole on ICGA, with subretinal/intraretinal fluids observed on optical coherence tomography (OCT) or leakage on fluorescein angiography (FA)
2. Received three continuous monthly intravitreal injections of 0.5 mg conbercept followed by as-needed injections
3. Pro re nata (PRN). Reinjection was considered if any intraretinal or subretinal fluid was observed after the third injection.
4. Underwent intravitreal conbercept injections as the primary treatment for PCV and completed at least six months of monthly follow-up exams after the first treatment
5. Aged 50 and older

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
45

Key exclusion criteria
1. Angioid streaks, multifocal choroiditis, punctate inner choroidopathy, pathologic myopia, retinal angiomatous proliferation or other diseases that can cause choroid neovascularization
2. The presence of any other ocular diseases that might affect visual acuity
3. Received any other treatment, including thermal laser photocoagulation, submacular surgery, intravitreal any other anti-VEGF drugs, and photodynamic therapy (PDT)

Date of first enrolment
01/11/2014

Date of final enrolment
01/06/2016

Locations

Countries of recruitment
China

Study participating centre
Zhongshan Ophthalmic Center
Sun Yat-sen University
State Key Laboratory of Ophthalmology
54 South Xianlie Road
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Sponsor information

Organisation
Sun Yat-sen University

Sponsor details
State Key Laboratory of Ophthalmology
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China
510060

Sponsor type
Hospital/treatment centre

Website
http://www.zocophlab.com/

ROR
https://ror.org/0064kty71

Funder(s)

Funder type
Research organisation

Funder Name
The National Natural Science Foundation of China

Funder Name
The Fundamental Research Funds of the 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 by pengyuting08@163.com

IPD sharing plan summary
Not provided at time of registration