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Comparison between conbercept and ranibizumab for treatment of neovascular age-related macular degeneration

Submission date
12/08/2016

Recruitment status
No longer recruiting

Registration date
24/08/2016

Overall study status
Completed

Last Edited
24/08/2016

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) is one of the leading causes of blindness in elderly people in Western countries. In recent years, the incidence of AMD in China has also increased. Wet AMD is caused by abnormal blood vessels growing in the eye. Vascular endothelial growth factor (VEGF) is one of the chemicals responsible for the growth of these blood vessels. Anti-VEGF medicines block this chemical, stopping it from producing blood vessels and preventing wet AMD from getting worse. Conbercept is an anti-VEGF drug that blocks all the different forms of VEGF-A, VEGF-B, VEGF-C and placenta growth factor (PlGF), whereas ranibizumab only blocks VEGF-A. The aim of this study is to compare conbercept and ranibizumab for the treatment of wet AMD.

Who can participate?
Patients aged 51–85 with active wet AMD in one eye

What does the study involve?
Participants are randomly allocated to be treated with either conbercept or ranibizumab. The interval between treatments is individually tailored based on the disease activity of each patient. Patients are treated no more frequently than every 4 weeks and no less frequently than every 12 weeks. If there are no signs of active disease, the period to the next treatment is extended by 2 weeks, up to a maximum interval of 12 weeks. Visual acuity (clarity of vision) is measured in both groups after one year.

What are the possible benefits and risks of participating?
No benefits are expected for the participants, but this study will improve the future treatment of AMD patients. Patients receiving an injection of any of the drugs may experience less severe side effects related to the pre-injection preparation procedure. These side effects may include eye pain, subconjunctival hemorrhage (bloodshot eye), vitreous floaters, irregularity or swelling of the cornea, inflammation of the eye, and visual disturbances. There is no additional risk involved in this study.

Where is the study run from?
1. The First Hospital of Qiqihar City (China)
2. The Second Affiliated Hospital of Harbin Medical University (China)
3. Peking Union Medical College Hospital (China)
4. The Third Affiliated Hospital of Qiqihar Medical University (China)

When is the study starting and how long is it expected to run for?
May 2014 to May 2016

Who is funding the study?
1. The First Hospital of Qiqihar City (China)
2. National Natural Science Foundation of China (China)
3. Research to Prevent Blindness (USA)

Who is the main contact?
Dr Jinglin Cui

Contact information

Type(s)
Scientific

Contact name
Dr Jinglin Cui

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Additional identifiers

Protocol serial number
2006… 003

Study information

Scientific Title
Comparison of effectiveness and safety between conbercept and ranibizumab for treatment of neovascular age-related macular degeneration

Study objectives
Conbercept is better than ranibizumab for the treatment of neovascular age-related macular degeneration.

Ethics approval required

Old ethics approval format

Ethics approval(s)
The First Hospital of Qiqihar institutional review board, 02/05/2014, ref: FHQQ2006-003

Study design
Multicenter retrospective randomly selected study with a noninferiority limit of five letters

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Age-related macular degeneration

Interventions
Between May 2014 and May 2015, 180 patients were randomly collected in a 1:1 ratio for treatments using conbercept or ranibizumab (n=90 in each cohort) from these four centers. These patients were randomly picked up from the patients of conbercept or ranibizumab groups without any information except the names of drugs. The patients selectively received intravitreal injections of conbercept 0.5 mg (0.05 ml) or ranibizumab 0.5 mg (0.05 ml) following a TREX protocol. Intravitreal injections were completed by experienced ophthalmologists and were masked. According to TREX management, beginning at the third monthly treatment, the interval between treatments was individually tailored based upon the exudative disease activity of each patient. Patients were treated no more frequently than every 4 weeks and no less frequently than every 12 weeks. An Inactive CNV lesion was achieved upon resolution of intraretinal and subretinal fluid on the optical coherence tomography (OCT) examination and upon resolution of subretinal and intraretinal hemorrhage related to exudative AMD, as determined by fundus examination. If there were no signs of active neovascular disease, the period to the next treatment was extended by 2 weeks, up to a maximum interval of 12 weeks.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Conbercept, ranibizumab

Primary outcome(s)
Best-corrected visual acuity (BCVA), as determined using the ETDRS chart at one year

Key secondary outcome(s))
1. The number of injections counted at the end of one year follow-up
2. Retinal thickness measured at every visit by OCT
3. Leakage of CNV measured at every visit by fundus fluorescein angiography (FFA)
4. Ocular complications measured at every visit by ophthalmologist examination

Completion date
01/05/2016

Eligibility

Key inclusion criteria
1. Age 51–85 years
2. Previously untreated active neovascular AMD in one eye
3. Absence of other ocular diseases determined by examination using a tonometer, slit lamp biomicroscope and ophthalmoscope
4. Lack of polypoidal choroidal vasculopathy (PCV) as determined by indocyanine green angiography (ICGA)
5. Total area of the subretinal hemorrhage and fibrosis comprised less than 50% of the total lesion

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Other serious illness
2. Systematic diseases
3. Polypoidal choroidal vasculopathy (PCV)
4. Subretinal hemorrhage and fibrosis comprised more than 50% of the total lesion

Date of first enrolment
02/05/2014

Date of final enrolment
01/05/2015

Locations

Countries of recruitment
China

Study participating centre
The First Hospital of Qiqihar City
China
161005

Study participating centre
The Second Affiliated Hospital of Harbin Medical University
China
150086

Study participating centre
Peking Union Medical College Hospital
China
100730

Study participating centre
The Third Affiliated Hospital of Qiqihar Medical University
China
161000

Sponsor information

Organisation
The First Hospital of Qiqihar City

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The First Hospital of Qiqihar City

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
Research to Prevent Blindness

Alternative Name(s)
Research To Prevent Blindness, Inc., RPB

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request