IRB of Beijing Tiantan Hospital, Capital Medical University
Approval Letter

Ethics approval No.  KY2015-031-02

Title of Project (No.): The individualized therapy in patients with neuromyelitis optica spectrum disorders treated by azathioprine (No. 2011BAI08B02)

Sponsor/CRO Department of Neurology, Beijing Tiantan Hospital

Research type

| □ Clinical trial of drugs Type:       | □ Clinical trial of Medical apparatus and instrument Type: |
| □ Phase I                           | □ Type I                                                  |
| □ Phase II                          | □ Type II                                                 |
| □ Phase III                         | □ Clinical practice                                      |
| □ Phase IV                          | □ Clinical validation                                    |

Clinical research

Drugs

Medical device

Clinical techniques

Observational study

Research type

Type:

□ Phase I

□ Phase II

□ Phase III

□ Phase IV

□ Drugs

□ Medical device

□ Clinical techniques

□ Observational study

□ Type I

□ Type II

□ Type III

PI/Department Xinghu Zhang/Neurology

Review Date 2015.12.28

Review Place Beijing Tiantan Hospital

Documents examined by IRB

Application for review of scientific research project
Research protocol (version V1.0, date: 2015.12.10)
Informed consent (version V1.0, date: 2015.12.10)
Case Report Form (version V1.0, date: 2015.12.10)
Beijing city science and technology plan
List of project PI and participants and their vitae
Drug label of azathioprine
Work foundations of the research
Request for review
Clinical research protocol (version V2.0/2016.01.26)
Informed consent (version V2.0/2016.01.26)

Review mode ☑ Quick review  □ Conference review

Review Committee Xiaoqiu Shao, Yangang Tian

Review comments

Based on the State Food and Drug Administration <Guidelines for Ethical Review of Drug Clinical Trials> (2010), <Good Clinical Practice> (2003), <Regulations of Clinical trials of Medical Devices>(2004), Health Ministry <Medical Technology Applications Management Approach>(2009), World Medical Association <Declaration of Helsinki>, and Council for International Organizations of Medical Sciences <International Ethical Guidelines for Biomedical Research Involving Human Subjects>, this study was reviewed.

The study “The individualized therapy in patients with neuromyelitis optica spectrum disorders treated by azathioprine” was approved by the IRB of Beijing Tiantan Hospital.

Annual/Periodic follow-up review date Annual/Periodic follow-up review should be submitted before 01-29/2017 (Frequency: 1 year)
Declarations:
1. The validity period of the approval letter: valid for 2 years after approval.
2. The responsibility, manning, operating procedures and records are in accordance with guidelines of GCP and ICH GCP which were issued by CFDA, and comply with the relevant laws and regulations.
3. The study should be performed in consistence with approved protocols, GCP and the declaration of Helsinki.
4. For disapproved, suspended or terminated protocols, the sponsor and researcher could submit a written complaint for re-examine.
5. Before modification of the clinical study protocol and informed consent, or replacement of the principal investigator, please promptly notify the IRB to re-examine.
6. If unexpected adverse events or serious adverse events affect the risk and/or benefit of this study, you should promptly report them to IRB.
7. Serious or continuous protocol deviation should be reported to IRB timely.
8. Annual/Periodic follow-up review: annual/Periodic follow-up review should be submitted one month before deadline.
9. Please submit report if you have completed the study.
10. Any questions during application please login: www.bjtth.org/Home/ → IRB.