

# A prospective cohort study on incidence and outcome of patients with post-stroke depression in China

<b>Submission date</b>	<b>Recruitment status</b>	<input checked="" type="checkbox"/> Prospectively registered
11/12/2007	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
21/12/2007	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
24/01/2019	Mental and Behavioural Disorders	

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Wang Yongjun

### Contact details

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## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

A prospective cohort study on incidence and outcome of patients with post-stroke depression in China

## **Acronym**

PRIOD- China

## **Study objectives**

1. Incidence of Post-Stroke Depression (PSD) in China may be different between 3 months and 6 months following onset of stroke
2. Patients with PSD may have poorer outcome than patients without PSD
3. Incidence of PSD may be correlated with stroke subtype, lesion location and other risk factors

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Tiantan Hospital Ethics Committee. Date of approval: 12/05/2008

## **Study design**

Multi-centre, observational, prospective, nested case-control study.

## **Primary study design**

Observational

## **Study type(s)**

Not Specified

## **Health condition(s) or problem(s) studied**

Post-stroke depression

## **Interventions**

1. The participants are classified into the following groups:

Group A: Stroke inpatients with PSD during follow up at 3 months or 6 months

Group B: Stroke inpatients without PSD during follow up at 3 months or 6 months

2. Diagnostic process & criteria:

2.1. Assessment through scales:

2.1.1. Hamilton Rating Scale for Depression (HRSD). HRSD is used as preliminary screening scale. Trained qualified neurological doctors make standard depression diagnosis of all doctor-visitors with  $\geq 8$  HRSD scores. Timepoints of assessment: Baseline at 14 days, 3, 6 and 12 months following onset

2.1.2. World Health Organization-Composite International Diagnostic Interview (WHO-CIDI).

Trained qualified neurological doctors make standard depression diagnosis of all doctor-visitors with  $\geq 8$  HRSD scores through CIDI at 3 and 6 months.

2.2. Patient self-assessment scale. Patients assess their mental state through BDI-13 scale biweekly for 3 months and monthly during 3 months - 1 year. Assessment results are recorded in follow-up diary. In case of  $BDI \geq 5$  during this period, patients should visit hospital for follow-up and CIDI diagnosis by trained qualified neurological doctors.

3. Possible risk factors will be compared between group A and group B, these will include:

3.1. Stroke subtype

3.2. National Institutes of Health Stroke Scale (NIHSS) at 12 months

3.3. Medical history

3.4. Complications

3.5. Lesion location

4. Outcome will be compared between group A and group B, these will include:

4.1 Modified Rankin Scale (mRS) at 3, 6 and 12 months

4.2 Quality of life: Medical Outcome Study Short Form 36 (SF-36) at 12 months

4.3 Stroke recurrence at 3, 6 and 12 months

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome(s)**

1. Onset: Incidence of depression within 3 months and 6 months of stroke onset

2. Scale score: Score tendency based on HRSD scale within 14 days, 3 months, 6 months, and 1 year of stroke onset

## **Key secondary outcome(s)**

1. Quality of life: Medical Outcome Study Short Form 36 (SF-36)

2. mRS score

## **Completion date**

01/06/2009

# **Eligibility**

## **Key inclusion criteria**

1. New stroke onset

2. Stroke onset time: Within 14d from doctor-visiting date

3. Patients age 18 years or older

4. Sign informed consent, cooperate with examination, and complete follow-ups

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

## **Age group**

Adult

## **Lower age limit**

18 years

## **Sex**

All

## **Key exclusion criteria**

1. Unable to complete examination due to the influence of eyesight, hearing, expression, consciousness, and apprehension

2. Stroke patient presenting no sign or symptom

**Date of first enrolment**

10/01/2008

**Date of final enrolment**

01/06/2009

## Locations

**Countries of recruitment**

China

**Study participating centre**

Department of Neurology of Beijing Tiantan Hospital

Beijing

China

100050

## Sponsor information

**Organisation**

Beijing Tian Tan Hospital, Capital Medical University (China)

**ROR**

<https://ror.org/003regz62>

## Funder(s)

**Funder type**

Government

**Funder Name**

Wyeth pharmaceuticals

**Funder Name**

Minister of the Science and Technology of the People's Republic of China, National Key Technology R&D Program (ref: 2006BA101A11)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#"><u>Results article</u></a>	results	01/06/2012		Yes	No
<a href="#"><u>Results article</u></a>	results	08/01/2019		Yes	No
<a href="#"><u>Participant information sheet</u></a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes