

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 ≥ 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 ≥ 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?
Results article	results	01/06/2012		Yes	No
Results article	results	08/01/2019		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes