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

Submission date	Recruitment status
11/12/2007	No longer recruiting
Registration date	**Overall study status**
21/12/2007	Completed
Last Edited	**Condition category**
24/01/2019	Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Case-control study

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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>=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 measure
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

Secondary outcome measures
1. Quality of life: Medical Outcome Study Short Form 36 (SF-36)
2. mRS score

Overall study start date
10/01/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2,500

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)

Sponsor details
No.6 Tiantanxili
Chongwen District

Beijing
China
100050

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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