ISRCTN07057952 https://doi.org/10.1186/ISRCTN07057952

Clopidogrel of loading dosage to treat acute ischaemic stroke in China (CLASS-CHINA)

Submission date	Recruitment status	[ ] Prospectively registered
05/03/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/03/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/02/2010	Circulatory System	[ ] Record updated in last year

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
CLASS-CHINA-2007-10-08

Study information

Scientific Title
Clopidogrel of loading dosage to treat acute ischaemic stroke in China (CLASS-CHINA): A randomized double-blind parallel controlled clinical trial

Acronym
CLASS-CHINA

Study objectives
Early recurrence of ischemic stroke/transient ischaemic attack (TIA) within 7 days occurs at a rate of about 2-8%, and deterioration (Stroke in Progression, SIP) is known to occur at about 30% or an even higher rate. In addition to thrombolysis, aspirin is the only proved effective agent for patients with acute ischemic stroke. However, the net benefit of aspirin is small. There is therefore a medical need to ensure a better protection against the early recurrence or deterioration of ischemic stroke.

Clopidogrel is superior to aspirin for second prevention for ischemic stroke, and pharmacokinetic data showed that conventional regimen of clopidogrel administration (75 mg/d) need 7 days to reach the optimal platelet inhibition effect, while 300 mg loading dose regimen, i.e. 300 mg initiation followed by 75 mg/d can reach the maximum platelet inhibition effect within 3 hours. Our pilot trial demonstrated a clear benefit trend of loading dose clopidogrel (300 mg) better than daily 75 mg of clopidogrel in patients with acute cerebral infarction/TIA. Therefore, we hypothesized that loading dose clopidogrel is effective and safe for patients with acute cerebral infarction caused by atherothrombosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the First Affiliated Hospital, Sun Yat-Sen University Guangzhou. Date of approval: 07/01/2008.

Study design
Multicenter, randomized, double-blind placebo controlled, parallel group study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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
Acute ischaemic stroke

Interventions
Two arms:
1 Loading dose (LD) group: patients will receive a 300 mg loading dose of clopidogrel right after randomization, followed by daily 75 mg clopidogrel for the next 27 days (total 28 days)
2 Routine dose group: patients will receive 75 mg clopidogrel and 3 tablets of placebo right after randomization, followed by daily 75 mg clopidogrel for the next 27 days (total 28 days)

Both arms will be given basic treatments at the discretion of the responsible doctor, including anti-hypertension drugs, statins, neuroprotetives, etc, except for aspirin or any other antiplatelet drugs. Chinese herbal products affecting platelet functions cannot not be prescribed.

During the observation period, if patients experience SIP or recurrence of ischemic stroke, clopidogrel may be stopped, and other antithrombotic therapy, i.e. anticoagulants, or others may be used at the discretion of the responsible doctor.

Please note that as of 08/02/10 the anticipated end date of this trial has been updated from 31 /08/09 to 31/05/10. Due to issues with patient recruitment, enrollment in this trial has been suspended. An intermediate analysis will be carried out in May 2010, once the follow up period for all patients is competed.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Clopidogrel

Primary outcome measure
Stroke recurrence or SIP (evaluated by the National Institutes of Health Stroke Scale [NIHSS]) within 7days.

Secondary outcome measures
1. Death or dependence (modified Rankin Scale [mRS] >=3) at 28 and 90 days
2. Death or stroke recurrence within 28 days
3. Stroke recurrence, acute myocardial infarction or vascular death with 28 days
4. Bleeding: Life-threatening bleeding, major bleeding and minor bleeding

Overall study start date
28/02/2008

Completion date
31/05/2010

Eligibility

Key inclusion criteria
1. Aged 18-80 years
2. Ischemic stroke (IS) within 48 hrs with evidence of computerised tomography (CT) or magnetic resonance imaging (MRI)
3. Satisfying the criteria of partial anterior circulation infarction (PACI) of Oxfordshire Community Stroke Project (OCSP) classification, and large artery atherothrombosis (LAA) of TOAST (the Trial of Org 10172 in Acute Stroke Treatment) classification
4. Informed consent of patient

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
600

Key exclusion criteria
1. Patients planned for thrombolysis
2. Any of the following:
2.1. Cardiogenic cerebral embolism
2.2. Lacuna cerebral infarction
2.3. Total anterior circulation cerebral infarction
2.4. Posterior circulation cerebral infarction
2.5. Cerebral infarction of the etiology rather than atherothrombosis and unidentified etiology
3. History of allergic reaction to clopidogrel
4. Patients regularly took oral anticoagulants (OAC), heparin or molecular weight heparin (LMWH), thienopyridine (clopidogrel or ticlopidine), aspirin (acetylsalicylic acid) >50 mg/d, Aggrenox® before the onset; or patients who need long-term use of drugs that affect platelet functions
5. History of bleeding disorders; clinically significant or persistent thrompocytopenia or neutropenia.
6. Women who are pregnant or breast-feeding
7. Patients with planned surgery within the next 1 month; with a recent operation or trauma history.
8. Severe systematic disorders i.e. heart, lung, liver, kidney diseases, or malignant tumor; or severe gastrointestinal disorder affecting the absorption of drug
9. Enrolled in other clinical trials within the past 3 months

Date of first enrolment
28/02/2008

Date of final enrolment
31/05/2010

Locations

Countries of recruitment
China

Study participating centre
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Sponsor information

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University/education

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Funder(s)

Funder type
University/education

Funder Name
Jinan University Guangzhou (China)

Funder Name
The First Affiliated Hospital, Sun Yat-Sen University, Guangzhou (China)

Funder Name
Sanofi-Aventis (clopidogrel and placebo are offered by Sanofi-Aventis) (France)

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