

Gastrodin prevents cognitive decline related to cardiopulmonary bypass

Submission date 25/02/2006	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 25/04/2006	Overall study status Completed	☐ Protocol
Last Edited 11/01/2021	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☒ 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

ClinicalTrials.gov (NCT)
NCT00297245

Protocol serial number
FWA00007304

Study information

Scientific Title
Gastrodin prevents cognitive decline related to cardiopulmonary bypass

Study objectives

Cardiopulmonary bypass (CPB) is associated with significant cerebral morbidity. The incidence of cognitive decline related to CPB ranges from 20% to 80%. However, there is no effective method to prevent the decline. We postulate that gastrodin would attenuate the causative parameters of cognitive dysfunction related to CPB and would be an effective drug to prevent the decline as a result.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Ethics Committee at Tongji Medical College on 19/01/2006, reference number: FWA00007304

Primary study design

Interventional

Study design

Double-blind, randomized controlled study

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Neurocognitive decline related to CPB

Interventions

Patients are randomized to receive either one the following interventions:

1. Gastrodin (40 mg/kg in 50 ml saline) will be injected intravenously with a pump within 45 minutes after induction of anesthesia
2. Saline 50 ml will be injected intravenously with a pump within 45 minutes after induction of anesthesia

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Gastrodin

Primary outcome(s)

Neurocognitive function

Key secondary outcome(s)

Safety of gastrodin

Completion date

01/06/2006

Eligibility

Key inclusion criteria

Adult patients (18 to 65 years) that have undergone mitral valve replacement surgery

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

200

Key exclusion criteria

1. Patients who have thrombosis in left atrium
2. A history of symptomatic cerebrovascular disease
3. Diabetes
4. Psychiatric illness
5. Renal disease or active liver disease
6. Less than a seven-grade education or those who cannot read will be excluded

Date of first enrolment

01/03/2006

Date of final enrolment

01/06/2006

Locations

Countries of recruitment

China

Study participating centre

1277 Jiefang Street

Wuhan

China

430022

Sponsor information

Organisation

Tongji Medical College (China)

ROR

<https://ror.org/00p991c53>

Funder(s)

Funder type

Research organisation

Funder Name

Supported by Grant (30271255) from the National Science Foundation of China.

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	01/02/2011	11/01/2021	Yes	No