ISRCTN47168298 https://doi.org/10.1186/ISRCTN47168298

Gastrodin prevents cognitive decline related to cardiopulmonary bypass

Submission date	Recruitment status	[ ] Prospectively registered
25/02/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/04/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/01/2021	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Shihai Zhang

Contact details
1277 Jiefang Street
Wuhan
China
430022

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00297245

Secondary identifying numbers
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

Study design
Double-blind, randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

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 measure
Neurocognitive function

Secondary outcome measures
Safety of gastrodin

Overall study start date
01/03/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

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)

Sponsor details
13 Hangkong Road
Wuhan
China
430030

Sponsor type
Hospital/treatment centre

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

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