

The relations between location and outcome in stereotactic neurosurgery for drug abuse

Submission date 19/01/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 17/02/2011	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 17/02/2011	Condition category Surgery	☐ Individual participant data ☐ 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

Protocol serial number
2007BAI0703

Study information

Scientific Title
A randomised blinded trial of nucleus accumbens ablation to treat opiate dependence in humans: location correlates with outcome

Study objectives
Surgical interventions within the nucleus accumbens are reported to have variable rates of efficacy and complications for a range of neuropsychiatric illnesses. We hypothesize that slight

variations in lesion location may have an important influence on clinical outcome. To investigate the optimal lesion site, we established a prospective randomised double-blinded trial to analyze opiate abstinence and complication rate in different radiofrequency ablation lesion locations within the nucleus accumbens (NAc).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Fourth Military Medical University approved on the 15th October 2003.

Study design

Randomised single centre prospective double-blinded interventional clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Functional neurosurgery for drug addiction

Interventions

1. Radiofrequency ablation of the NAc
2. Different lesioning location and volume within NAc in four groups
3. Abstinence from opioid use and adverse events related to operation
4. Neuropsychiatric functional changes, measured by formal neuropsychiatric instruments

Follow up length: 4 years

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

Abstinence from opioid use, measured by morphine urinalysis and naloxone testing in the fourth post-operative year

Key secondary outcome(s)

1. Complications in stereotactic surgery (e.g fever, nausea/emesis, seizure, infection, intracranial haemorrhages)
2. Possible neuropsychiatric change related to NAc ablation: memory, motivation, emotion, olfactory sensation

After operation, the secondary outcomes were measured at six month intervals and extended for four years.

Completion date

30/11/2004

Eligibility

Key inclusion criteria

1. Heroin abuse using 0.3 - 1.0 g daily for at least 3 years by intravenous injection with or without concomitant nasal inhalation
2. Failure of multiple other treatment modalities
3. Ages between 18 and 50 years, either sex
4. Completion of detoxification treatment preoperatively with no somatic symptoms of withdrawal and negative morphine urinalysis and naloxone tests

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Inability to give informed consent
2. Human immunodeficiency virus (HIV), hepatitis B virus (HBV) or hepatitis C virus (HCV) virus carrier
3. Developmental delay, cognitive impairment, personality disorders and neuropsychiatric diseases other than addiction

Date of first enrolment

01/01/2004

Date of final enrolment

30/11/2004

Locations

Countries of recruitment

China

Study participating centre

1# Xinsi Road, Baqiao District.

Xi'an

China
710038

Sponsor information

Organisation

Ministry of Science and Technology (China)

ROR

<https://ror.org/027s68j25>

Funder(s)

Funder type

Government

Funder Name

Ministry of Science and Technology (China) (ref: 2007BAI0703)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration