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

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Functional neurosurgery for drug addiction

Interventions
1. Radiofrequency ablation of the NAc
2. Different lesioning location and volumn 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 measure
Abstinence from opioid use, measured by morphine urinalysis and naloxone testing in the fourth post-operative year

Secondary outcome measures
1. Complications in stereoctactic 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.

Overall study start date
01/01/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

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)

Sponsor details
15B Fuxin Road
Beijing
China
100862

Sponsor type
Government

Website
http://www.most.gov.cn/

ROR
https://ror.org/027s68j25

Funder(s)

Funder type

Government

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

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