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The postoperative pain management of stereotactic radiosurgery in patients with brain metastases from lung cancer

Submission date 12/02/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 07/03/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 06/03/2025	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
The mechanism of postoperative pain after stereotactic radiosurgery (SRS) for lung cancer brain metastases is complex and involves a variety of factors and pathways, including direct compression of the tumour to stimulate the nerves, bone metastasis of the lesion, secretion of tumour factors to induce pain, and other parts of the patient will also suffer from pain due to psychological and mental factors. This study aims to investigate the clinical effect of the combination of morphine sulfate sustained-release tablets and Banxia Baizhu Tianma Decoction in the postoperative pain management of SRS in patients with brain metastases from lung cancer.

Who can participate?
Patients with brain metastases from lung cancer.

What does the study involve?
Participants were randomly grouped. The control group was treated with morphine sulfate sustained-release tablets for analgesia after SRS, and the research group was treated with morphine sulfate sustained-release tablets and Banxia Baizhu Tianma Decoction after SRS.

What are the possible benefits and risks of participating?
The results of this study will demonstrate the clinical effect of the combination of morphine sulfate sustained-release tablets and Banxia Baizhu Tianma Decoction in the postoperative pain management of SRS in patients with brain metastases from lung cancer.

Where is the study run from?
Hebei Provincial Traditional Chinese Medicine Hospital (China)

When is the study starting and how long is it expected to run for?
January 2021 to July 2024

Who is funding the study?
Hebei Provincial Traditional Chinese Medicine Hospital (China)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Clinical effects of the combination of morphine sulphate sustained-release tablets and Banxia Baizhu Tianma Decoction in the postoperative pain management of stereotactic radiosurgery in patients with brain metastases from lung cancer

Study objectives
To investigate the clinical effect of the combination of morphine sulfate sustained-release tablets and Banxia Baizhu Tianma Decoction in the postoperative pain management of stereotactic radiosurgery (SRS) in patients with brain metastases from lung cancer.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 20/05/2024, Hebei Provincial Traditional Chinese Medicine Hospital (No. 389 of Zhongshan East Road, Shijiazhuang, 050000, China; +86 (0)311-69095316; hbzylczyx@163.com), ref: Not applicable

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Postoperative pain management of SRS in patients with brain metastases from lung cancer

Interventions
A total of 269 patients with brain metastasis of lung cancer admitted to the hospital from January 2021 to July 2024 were selected as the study subjects by convenience sampling method. They were randomly grouped according to the numerical sampling method. The control group (134 cases) was treated with morphine sulfate sustained-release tablets for analgesia after SRS, and the research group (135 cases) was treated with morphine sulfate sustained-release tablets and Banxia Baizhu Tianma Decoction after SRS.

Both groups of patients used conventional interventions for intermediate and advanced cancer, such as dietary interventions, exercise regulation, lifestyle correction and so on. On this basis, patients in the control group used morphine sulfate sustained-release tablets (Menti [China] Pharmaceutical Co Ltd, specification: 30 mg/tablet, State Pharmaceutical Licence H10980062) for analgesic intervention, and the applied dosage was 1 tablet/times, 2 times/day. Patients in the research group were combined with Banxia Baizhu Tianma Decoction for analgesic treatment on the basis of the control group. Banxia Baizhu Tianma Decoction: 12 g of Pinellia ternata, 10 g of Gastrodia elata blume, 12 g of Poria cocos, 8 g of Red tangerine peel, 12 g of Largehead Atractylodes Rh, 6 g of Liquorice root, 2 slices of Ginger, and 3 jujubes. 1 dose per day, 400 mL of water decoction, 1 time in the morning and 1 time in the evening. Both groups of patients were treated for 2 weeks.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Morphine sulfate sustained-release tablets; Banxia Baizhu Tianma Decoction

Primary outcome(s)
The following primary outcome measures were assessed at 2 weeks after the intervention:
1. The analgesic effect after intervention was divided into complete relief (CR, patients' pain was completely relieved after medication), partial relief (PR, patients' pain was relieved after intervention and normal sleep was not affected), minor relief (MR, pain was improved after analgesia but it was not obvious, and patients' life and sleep were affected), and no relief (NR,

analgesia was ineffective); the total effective rate = (CR+PR)/total number of cases × 100%.
2. The incidence of adverse reactions in the process of analgesia between the two groups of patients, mainly including constipation, nausea and vomiting, drowsiness, urine retention and so on
3. Quality of life assessed using the Quality of Life Scale for Oncology Patients

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/07/2024

Eligibility

Key inclusion criteria
1. Diagnosed with brain metastasis of lung cancer with clear pathological results and a score of ≥4 on the Pain Level Assessment Scale
2. Clear consciousness to cooperate with the assessment of pain level and quality of life
3. No allergy to the study drugs

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
269

Key exclusion criteria
1. Allergic to the study drug
2. Drug addicts
3. Alcohol addicts
4. Respiratory depression
5. Psychiatric history

Date of first enrolment
01/01/2021

Date of final enrolment
31/07/2024

Locations

Countries of recruitment
China

Study participating centre
Hebei Provincial Traditional Chinese Medicine Hospital
China
050000

Sponsor information

Organisation
Hebei Provincial Traditional Chinese Medicine Hospital

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hebei Provincial Traditional Chinese Medicine Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request - further details to be added at a later date

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes