

# The efficacy, safety and cost-effectiveness analysis of morphine and hydromorphone in intrathecal drug deliver system for intractable cancer pain

<b>Submission date</b> 03/01/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/01/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/02/2016	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Intractable cancer pain (that is pain that is resistant to the effects of painkillers) is a difficult medical problem. Intrathecal analgesia (that is, painkiller injected into the spinal cord) has emerged as a key therapeutic option for pain relief for patients for which other treatment avenues have not worked as well as patients on high doses of analgesia (painkiller) suffering from unacceptable side effects. Hydromorphone, is a opiod drug with effects similar to that of morphine, but is more potent and acts more quickly due to its greater lipophilic properties (that is, it is more able to dissolve in lipids, or fats). But the comparison between hydromorphone and morphine in how well they work (efficacy), safety, and pharmacoeconomics analysis research (that is, comparing the value of one drug compared to another) is rare in China. The aims of this study was to observe the effects, security and pharmacoeconomics of morphine and hydromorphone in the treatment of intractable cancer pain.

### Who can participate?

Adults with cancer suffering from intractable cancer pain

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in group 1 are given hydromorphone via a intrathecal catheter. Those in group 2 are given morphine via a intrathecal catheter. The pain experienced after treatment is assessed for each patient every day for the next 3 months.

### What are the possible benefits and risks of participating?

The immediate direct benefit to those taking part is better pain management and a free intrathecal drug delivery system (IDDs). After treatment, patients' quality of life may improve. The main risk of this study is surgical complications from inserting the intrathecal catheter including bleeding, neurological injury, infection, cerebrospinal fluid (CSF) leakage and shredded catheters.

Where is the study run from?

Pain Management Department, Xinhua Hospital (affiliated to Shanghai Jiaotong University, School of Medicine)

When is the study starting and how long is it expected to run for?

December 2015 to December 2016

Who is funding the study?

Chinese association for the study of pain, the minimally invasive interventional group

Who is the main contact?

Professor Ke MA

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## Contact information

### Type(s)

Scientific

### Contact name

Prof Ke MA

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

Scientific Title

The efficacy, safety and cost-effectiveness analysis of morphine and hydromorphone in intrathecal drug delivery system for intractable cancer pain: multicenter, randomized single-blind, controlled study.

### **Study objectives**

1. Morphine and hydromorphone are effective and safe when administered using the intrathecal drug delivery system for intractable cancer pain patients.
2. Morphine and hydromorphone administered using the intrathecal drug delivery system can improve the quality of life and reduce the oral pain-related drugs dosage of cancer pain patients.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Xinhua hospital Ethics Committee Affiliated to Shanghai Jiaotong University School of Medicine, 08/09/2015, ref: XHEC-C -2015-018-2

### **Study design**

Multicenter single-blinded randomized controlled clinical study

### **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 contact details to request a participant information sheet

### **Health condition(s) or problem(s) studied**

Cancer pain

### **Interventions**

An intrathecal catheter is placed at the L4/5 or L3/4 level and the catheter is passed under fluoroscopic guidance to the T10 or T11 vertebral level. Then, a tunneled subcutaneous catheter plus a subcutaneous port, with an external infusion pump system were implanted.

240 patients with cancer pain were randomized and assigned into 2 equal groups:

1. Hydromorphone group (n = 120)
2. Morphine group (n = 120)

The duration of follow-up is 3 months post-treatment.

### **Intervention Type**

Procedure/Surgery

**Primary outcome measure**

1. Pain after treatment, measured using the visual analogue score (VAS) every day during 3 months after treatment
2. Drug cost-effectiveness at 1, 2 and 3 months after treatment

**Secondary outcome measures**

1. The frequency, duration and degree of the flare pain everyday during 3 months after treatment
2. Intensity of anxiety experienced by patient. measured using the PHQ - 9 evaluation scale at 1, 2 and 3 months after treatment
3. Intensity of depression experienced by patient, measured by the GAD - 7 anxiety screening scale) at 1, 2 and 3 months after treatment
4. Quality of life measured by the quality of life score (SF - 36) at 1, 2 and 3 months after treatment

**Overall study start date**

01/12/2015

**Completion date**

31/12/2016

**Eligibility****Key inclusion criteria**

Cancer pain

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

240

**Key exclusion criteria**

1. Researchers think that there is any reason can't include
2. IDDS procedure contraindications
3. Uncooperative and unable to finish the self evaluation (PHQ - 9, GAD - 7 and SF-36)
4. Spinal deformity, intolerance to operation
5. The central infection, severe systemic infection
6. The blood coagulation dysfunction; severe liver and kidney dysfunction
7. Patient who has a history of drug abuse

**Date of first enrolment**

01/12/2015

**Date of final enrolment**

30/12/2016

**Locations****Countries of recruitment**

China

**Study participating centre**

**Pain Management Department, Xinhua Hospital affiliated to Medical School of Shanghai Jiaotong University**

No 1995 Kongjiang Road

Shanghai

China

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**Study participating centre**

**Pain Medicine Center, Nanjing Jinling Hospital,**

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**Study participating centre**

**Tiantan Hospital, Pain Department**

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**Study participating centre**

**Xijing Hospital, Pain Management Department**

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**Study participating centre**

**The First Affiliated Hospital, China Medical University**

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**Study participating centre**  
**The First Hospital affiliated to Medical School of Zhejiang University**  
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**Study participating centre**  
**Gulou Hospital**  
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Nanjing  
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210008

**Study participating centre**  
**The People's Hospital of Qinghai Province**  
Pain Management Department  
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China  
810007

**Study participating centre**  
**The First Hospital affiliated to Chongqing Medical College**  
No 1, Youyi Road  
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Chongqing  
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**Study participating centre**  
**The 2nd affiliated Hospital of Kunming Medical College**  
Pain Management Department

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**Study participating centre**  
**The Tenth Hospital affiliated to Tongji University**  
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**Study participating centre**  
**Tumor Hospital of Hennan province**  
Department of Pain Medicine  
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## **Sponsor information**

### **Organisation**

Chinese association for the study of pain, the minimally invasive interventional group

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### **Sponsor type**

Research organisation

### **ROR**

<https://ror.org/03tygvc25>

# **Funder(s)**

## **Funder type**

Research organisation

## **Funder Name**

Chinese association for the study of pain, the minimally invasive interventional group

# **Results and Publications**

## **Publication and dissemination plan**

The clinical trial will be finished at Mar 2017, and the paper will be finished and contributed to an appropriate journal in Jun 2017.

## **Intention to publish date**

30/06/2017

## **Individual participant data (IPD) sharing plan**

## **IPD sharing plan summary**

Data sharing statement to be made available at a later date