

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

Submission date 03/01/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/01/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/02/2016	Condition category 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 opioid 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

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Additional identifiers

Study information

Scientific Title

The efficacy, safety and cost-effectiveness analysis of morphine and hydromorphone in intrathecal drug deliver 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

31/12/2016

Eligibility

Key inclusion criteria

Cancer pain

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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
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Study participating centre

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Nanjing
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Study participating centre

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Sponsor information

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date