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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

Registration date
26/01/2016

Overall study status
Completed

Last Edited
02/02/2016

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

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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 paina 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

Primary study design
Interventional

Study design
Muiticenter single-blinded randomized controlled clinical study

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 3months after treatment
3. Intensity of depression experienced by patient, measured by the GAD - 7 anxiety screening

scale) at 1, 2 and 3months 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
China
200092

Study participating centre
Pain Medicine Center, Nanjing Jinling Hospital,
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Beijing
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No 127, West Changle Road
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The First Affiliated Hospital, China Medical University
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Study participating centre
The First Hospital affiliated to Medical School of Zhejiang University
Pain Management Department
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Study participating centre
Gulou Hospital
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Study participating centre
The People's Hospital of Qinghai Province
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The First Hospital affiliated to Chongqing Medical College
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Study participating centre
The 2nd affiliated Hospital of Kunming Medical College
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Study participating centre
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Study participating centre
Tumor Hospital of Hennan province
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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