ISRCTN60931429 https://doi.org/10.1186/ISRCTN60931429

Clinical study of the effect of oral administration of magnesium threoninate (L-TAMS) in morphine analgesia and tolerance

Submission date
11/01/2018

Recruitment status
No longer recruiting

Registration date
24/01/2018

Overall study status
Completed

Last Edited
14/02/2024

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Intractable cancer pain is a difficult medical problem. The drug morphine has emerged as a key treatment option for pain relief. Morphine is the main method of controlling cancer pain, but repeated morphine use lead to tolerance and the need to increase the dose for satisfactory results. A high dose of morphine could induce constipation, respiratory depression (slow and ineffective breathing), skin itching and other side effects. The aim of this study is to assess the effectiveness of magnesium threoninate (L-TAMS) on cancer pain in patients treated with morphine, to see whether it prevents morphine tolerance.

Who can participate?
Patients aged 18 to 80 years with cancer pain being treated with morphine

What does the study involve?
Participants are randomly allocated to two groups. Those in group 1 are given magnesium threonate (L-TAMS) for 12 weeks. Those in group 2 are given a placebo (dummy drug) for 12 weeks. Both groups are also treated with morphine. 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 possible benefits are that participant could have better pain relief. The main possible risk is a side effect of magnesium threoninate (L-TAMS).

Where is the study run from?
Xinhua Hospital (affiliated with Shanghai Jiaotong University School of Medicine) (China)

When is the study starting and how long is it expected to run for?
February 2018 to July 2019

Who is funding the study?
Xinhua Hospital (affiliated with Shanghai Jiaotong University School of Medicine) (China)

Who is the main contact?
Prof. Ke Ma

Contact information

Type(s)
Scientific

Contact name
Prof Ke Ma

Contact details
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200092

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
XINHUA2018-01

Study information

Scientific Title
Clinical trial of the effect of oral administration of magnesium threoninate (L-TAMS) in morphine analgesia and tolerance

Study objectives
1. Oral administration of magnesium threoninate (L-TAMS) is safe for intractable cancer pain patients.
2. The oral administration of magnesium threoninate (L-TAMS) can improve quality of life, enhance morphine analgesia, and prevent and inhibit morphine tolerance

Ethics approval required
Old ethics approval format

Ethics approval(s)
Xinhua Hospital Ethics Committee Affiliated to Shanghai Jiaotong University School of Medicine, 26/12/2017, ref: XHEC-C -2017-106

Study design
Single-center double-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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Cancer pain

Interventions
98 participants are randomly allocated to two groups. Those in group 1 (n = 49) are given magnesium threonate (L-TAMS) 1.5 g/day for 12 weeks. Those in group 2 (n = 49) are given placebo 1.5 g/day for 12 weeks. Both groups are treated with morphine. The pain experienced after treatment is assessed for each patient every day for the next 3 months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Magnesium threonate (L-TAMS)

Primary outcome measure
1. Pain, measured using the visual analogue score (VAS) every day during the treatment. The frequency and intensity of the pain outbreak every day during the treatment
2. The dosage of morphine per day during the treatment

Secondary outcome measures
1. Intensity of anxiety, measured using the PHQ-9 evaluation scale every day during the treatment
2. Intensity of depression, measured by the GAD-7 anxiety screening scale) every day during the treatment
3. Quality of life, measured by the quality of life score (QOL) every day during the treatment

Overall study start date
01/02/2018

Completion date

31/07/2019

Eligibility

Key inclusion criteria
1. Subjects voluntarily signed the informed consent
2. Patients suffering from cancer pain with treatment of morphine, aged from 18 to 80 regardless of gender
3. Survival time is expected to exceed 3 months
4. Moderate to severe pain, VAS >4 points or more, or outbreak of pain >3 times/day
5. Patients can follow the drug dose and follow-up plan
6. Patients can describe the symptoms, no serious infection, respiratory insufficiency and has the ability to cooperate
7. Non-allergic persons
8. No drug abuse or drug addiction
9. Non-lactating, pregnant women. Subjects who did not have a pregnancy plan within 1 month after the test
10. Patients did not participate in a drug test within 3 months before this test (including the test drug)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
98

Total final enrolment
116

Key exclusion criteria
1. Researchers think that there is any reason they can't be included
2. In poor situation, severe systemic infection or respiratory dysfunction and uncooperative
3. Suffering from severe respiratory system, cardiovascular system diseases, liver and kidney dysfunction, cancer
4. Patients who are allergic to magnesium threonate (L-TAMS)
5. Patient who has a history of drug abuse
6. Breastfeeding, gestational women or subjects who do not have a pregnancy plan within 1 month after the test
7. Patients who participated in a drug trial within 3 months before this trial
8. Patients does not meet the inclusion criteria

Date of first enrolment
01/02/2018

Date of final enrolment
31/01/2019

Locations

Countries of recruitment
China

Study participating centre
Pain Management Centre, Xinhua Hospital (affiliated with Shanghai Jiaotong University School of Medicine)
China
200092

Sponsor information

Organisation
Xinhua Hospital (affiliated with Shanghai Jiaotong University School of Medicine)

Sponsor details
No 1665 Kongjiang Road Yangpu District
Shanghai
China
200092

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04dzvks42

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Xinhua Hospital (affiliated with Shanghai Jiaotong University School of Medicine)

Results and Publications

Publication and dissemination plan
The paper will be finished and submitted to a high-impact peer reviewed journal of pain, such as Pain, Pain Physician, J of Pain and so on.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/01/2023	14/02/2024	Yes	No