

Direct effect of four different compounds on experimental pain

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35743

Source

ToetsingOnline

Brief title

Direct effect of four different compounds on experimental pain

Condition

- Other condition

Synonym

experimental pain

Health condition

het onderzoek betreft gezonde vrijwilligers waarbij wordt gekeken op de mate van opgewekte experimentele pijn na toediening van een medicament.

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: experimental pain medication

Outcome measures

Primary outcome

amount of pain expressed as e-VAS (electronic Visual Analogue Scale).

Secondary outcome

na

Study description

Background summary

Treatment of acute pain after surgery and chronic pain in cancer patients consists of many different modalities. Apart from various types of non-pharmacological interventions, most often therapy consists of administration of analgesics. However, in the past several non-analgesic compounds have been used in the perioperative setting to decrease postoperative pain sensation and therefore faster postoperative recovery and hospital discharge. Other substances have proved usefull in the treatment of metastatic bone pain en phantom limb pain. These products are known as adenosine, dexamethasone, zoledronic acid and salmon calcitonin.

Study objective

Although these products have been used extensively in patients, the effect of these medications on experimental pain sensation has never been investigated. There is little knowledge about any direct effect of these medications on pain perception. In the following study we want to investigate whether such a direct analgesic effect in experimentally provoked pain exists.

Study design

Placebo-controlled, double-blind, randomized, cross-over study.

Intervention

Volunteers will be randomly assigned to either first placebo group and a couple of weeks later treatment group or vice versa. All volunteers will undergo in total two series of pain tests: one treatment session and one placebo session in random order. The subjects will be unaware in which session they are participating.

Study burden and risks

A thermal stimulus will be applied on the volar side of the forearm of the participant. This may produce a short lasting red discoloration of the skin which will disappear in a couple of hours.

The administration of the substances is accompanied by several side-effects:

Adenosine

The most common side effects associated with the administration of adenosine include flushing, chest discomfort, bronchospasm and dyspnea, headache, gastrointestinal discomfort, bradycardia, AV-block and lightheadedness. Most of these effects are generally well tolerated and transient due to the short half life of the product (estimated to be less than 10s). Administration of the drug should occur under continuous monitoring of cardiac rhythm. In case a second or third degree AV-block develops, the administration of adenosine should be discontinued immediately.

Zoledronic acid

The use of zoledronic acid may be accompanied by headache, diarrhoea, nausea and vomiting. Furthermore bone pain, joint pain and muscle pain have been described as well as hypocalcemia. Very occasionally osteonecrosis of the jaw has been reported. This condition is more likely to develop after repeated infusion schemes. The intravenous use of bisphosphonates may be regularly associated with an influenza type of syndrome, characterized by bone pain, fever, fatigue and muscle rigidity.

Dexamethason

When given too rapidly, dexamethason may cause a perineal flushing reaction. This effect may be related to the phosphate buffer rather than the drug itself. Usual glucocorticoid side effects include gastrointestinal bleeding, impaired wound healing, increased blood glucose levels, and increased susceptibility to infection. These side effects are usually only seen in patients receiving steroids on long-term basis. Apart from these regular side effects, also insomnia and agitation have also been described, especially when given in the setting of postchemotherapy nausea prophylaxis.

Salmon calcitonin

During salmon calcitonin administration, facial flushing, nausea, vomiting, light sedation and dizziness may be observed. Twenty to thirty mins after infusion flushing of the face and chest may be seen. 4-6 hours after administration a predominantly asymptomatic hypocalcemia may develop.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

healthy volunteers of both sexes in the age range of 18-75 years.

Exclusion criteria

Unable to give written informed consent
Medical disease such as renal, liver, cardiac, vascular (incl. hypertension) or infectious disease
History of cerebro-vascular accident < 1 year
Pregnancy
Obesity (BMI > 30)

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	06-02-2012
Enrollment:	48
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Aclasta
Generic name:	Zoledronic acid
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Adenoscan
Generic name:	Adenosine
Registration:	Yes - NL outside intended use

Product type:	Medicine
Brand name:	Calcitonine-Sandoz
Generic name:	Salmon Calcitonin
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Dexamethasone
Generic name:	Dexamethasone
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO	
Date:	17-02-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	19-09-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register

EudraCT

CCMO

ID

EUCTR2011-000291-34-NL

NL35555.058.11