Pain management in renal colic; The efficacy of continuous intravenous administration of tramadol versus butylscopolamine. A double blinded, randomized placebo controlled, prospective multicenter trial.

Published: 02-10-2009
Last updated: 06-05-2024

Primary objective:Can a difference between the change in the perception of pain over time (0-60 minutes) between tramadol and butylscopolamine in renal colic be proven?Secundary objectives:- Can a difference in the decline in VAS-score over time (0-...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Urolithiases
Study type	Observational non invasive

Summary

ID

NL-OMON33885

Source
ToetsingOnline

Brief title
The efficacy of i.v administration of tramal versus buscopan in renal colic

Condition

- Urolithiases

Synonym
colic pain, renal colic

Research involving

Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Butylscopolamine, Painmanagement, Renal colic, Tramadol

Outcome measures

Primary outcome

Efficacy of treatment is defined as a decline of 10 mm or more on the horizontal Visual Analogue Scale. Differences between the tramadol and butylscopolamine groups will be calculated with change in VAS-score between T0 and T3(60 min)

Secondary outcome

Secundary objectives:

- Can a difference in the decline in VAS-score over time (0-240 minutes) between the tramadol group and the butylscopolamine group be proven?
The decline in VAS-score will be compared between the tramadol and butylscopolamine group at the different time intervals.

- Can the therapeutic efficacy of butylscopolamine compared to placebo over time (0-240 minutes) be proven?
A significant difference between the butylscopolamine group and the placebo

group will be marked as prove.

- Can the therapeutic efficacy of tramadol compared to placebo over time (0-240 minutes) be proved?
A significant difference between the tramadol group and the placebo group will be marked as prove.

- What are the side effects of continuous intravenous administered tramadol and to what extend do they occur?
Side -effects are being scored as present or absent. The presence of side-effects will be presented as a percentage of the total number of patients treated with studymedication.

- Is a difference in the need for of rescue-medication seen between the tramadol and the butylscopolamine group?

Study description

Background summary

Traditional treatment of renal colic is administration of an NSAID, combined with intravenous administration of butylscopolamine. This treatment often needs additional opioid analgesics to reach relief of pain. Opioids are administered when pain does not sufficiently declines after treatment with NSAID's and butylscopolamine. There for it takes longer to relief the renal colic pain.
This study investigates the efficacy of continuous intravenous administration of tramadol in renal colic pain and aims to support the results of Mortelmans

et al (J Endourol 2006;20:1010-1015).

Study objective

Primary objective:
Can a difference between the change in the perception of pain over time (0-60 minutes) between tramadol and butylscopolamine in renal colic be proven?

Secundary objectives:
- Can a difference in the decline in VAS-score over time (0-240 minutes) between the tramadol group and the butylscopolamine group be proven?
- Can the therapeutic efficacy of butylscopolamine compared to placebo over time (0-240 minutes) be proved?
- Can the therapeutic efficacy of tramadol compared to placebo over time (0-240 minutes) be proved?
- What are the side effects of continuous intravenous administered tramadol and to what extend do they occur?
- Is a difference in the need for of rescue-medication seen between the tramadol and the butylscopolamine group?

Study design

There has been chosen for a prospective, randomized, double-blinded, placebo-controlled, clinical trial. The study population consists of three groups. The tramadol group, the butylscopolamine group and the placebogroup. I refer for further information to the flowchart of this study.

Study burden and risks

The time and energy which has to be spent by the participants is negligible. Vital parameters will be measured non-invasive by the nursing staff at the different time intervals and the participants will have to score their pain on the VAS-score. Treatment with tramadol intravenous seems safe and side-effects are considered as minor. There for there will be no greater risk than in traditional treatment for renal colic for the participants.

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

Adults 18 years and older
Written and oral informed consent obtained
Mental capacity to make a will

Exclusion criteria

Pregnancy / lactation
Chronic tramadol use
Renal insufficiency, creatinine clearance < 10 ml/min
Hepatic insufficiency
Severe COPD / respiratory insufficiency
Intolerance to NSAID's and/or opioids
Monoamine oxidase inhibitors use, or within 2 weeks after withdrawal
Narrow-angle glaucoma
Intoxication with alcohol or other drugs
NSAID use < 8 hours before presentation
Hydronephrosis together with fever

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	120
Type:	Anticipated

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	butylscopolaminebromide
Generic name:	butylscopolaminebromide
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	diclofenac
Generic name:	diclofenac
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	metoclopramide
Generic name:	metoclopramide
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	piritramide

Generic name:	piritramide
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	tramadol
Generic name:	tramadol
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	02-10-2009
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	05-10-2009
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	ID
EudraCT	EUCTR2007-006198-98-NL
CCMO	NL18975.075.09