Pain treatment in renal colics; the role of Instanyl ® in prevention of hospitalization. A Clinical outcomes study.

Published: 18-10-2012
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Main objective: To evaluate the pain reduction in patients receiving Instanyl®Secondary objectives: To evaluate; the duration of pain reduction in patients receiving Instanyl®; the degree of adverse effects in patients receiving Instanyl®: whether...

Ethical review	Approved WMO
Status	Pending
Health condition type	Urolithiases
Study type	Interventional

Summary

ID

NL-OMON37827

Source
ToetsingOnline

Brief title
The role of Instanyl ® in renal colics

Condition

- Urolithiases

Synonym
colic pain, renal colic

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken

Source(s) of monetary or material Support: Farmaceutische industrie,Nycomed

Intervention

Keyword: fentanyl intranasal, Instanyl, Pain relief, Renal Colic

Outcome measures

Primary outcome

the main parameter is the pain reduction after 20 minutes measured on a 100 mm

VAS-score.

Secondary outcome

- The need for butylscopolamin after 20 minutes

- Adverse reactions are expressed as being present (=1) or being absent (=0)

- The time elapsed until butylscopolamin is administered.

- 2 weeks after participation it will be noted whether (=1) or not (=0) the

participant presented a second time with renal colics and was treated with

butylscopolamine.

Study description

Background summary

Renal colics are an acute and severe pain occurring when a renal stone obstructs the urinary flow in through the ureter. Standard treatment constists of NSAID*s. When the pain relief is insufficient, patients are administered butylscopolamine intravenously. This procedure is costly and inconvenient for the patient. Instanyl® is an opioid analgesic indicated for use in patients with breakthrough cancer pain. It could reduce pain in acute renal colics and reduce the need for butylscopolamine as it is fast and efficient.

Study objective

Main objective: To evaluate the pain reduction in patients receiving Instanyl®
Secondary objectives: To evaluate; the duration of pain reduction in patients

receiving Instanyl®; the degree of adverse effects in patients receiving Instanyl®: whether use of Instanyl® on-demand reduces the need for intravenous butylscopolamine in patients presenting with an acute renal colic.

Study design

Clinical outcomes study.

Intervention

Participants receive a nasal spray containing 59 microgram/dose Instanyl®. They are administered a single dose.

Study burden and risks

Potential benefits are the additional analgetics and potentially no need for butylscopolamine. The assosiated risks are the adverse events of Instanyl®. As with other opiods, the most serious risk is respiratory depression. The extend of the burden consists of; administration to the hospital; VAS-scores and measurements of blood pressure, pulse and oxygen every hour.

Contacts

Public
Isala Klinieken

Groot Weezenland 20
Zwolle 8000 GM
NL
Scientific
Isala Klinieken

Groot Weezenland 20
Zwolle 8000 GM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age: 18 years or older;Renal colic;Opioid naive;Informed consent obtained

Exclusion criteria

- Contra-indications for NSAID's or intranasal opioids;- Opioid tolerant patients

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2012
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Instanyl ®

Generic name:	fentanyl citrate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Tamsulosine
Generic name:	Diclofenac
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	18-10-2012
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	30-10-2012
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	EUCTR2012-001370-28-NL
CCMO	NL40180.075.12