Study protocol for a randomized clinical trial of a continuous butylscopolamine infusion versus a placebo in patients with a renal colic not responding to oral NSAIDs

Published: 11-08-2017
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The purpose of this study is to analyse the effect on pain reduction of butylscopolamine in a continuous intravenous infusion compared to a placebo in patients with renal colics not responding to oral NSAIDs.

Ethical review	Approved WMO
Status	Completed
Health condition type	Urolithiases
Study type	Observational non invasive

Summary

ID

NL-OMON47573

Source
ToetsingOnline

Brief title
BUSCOPAN

Condition

- Urolithiases

Synonym
urolithiasis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Analgetic, Buscopan, Colic, Renal

Outcome measures

Primary outcome

The primary endpoint is the pain reduction in Numerice Rating Scale score (NRS score), measured at at 0 hours, 1 hours, 4 hours, 8 hours and 24 hours.

Secondary outcome

The secondary endpoints are the side effects of the different medications, the amount of rescue medication, the rate of interventions in patients not responding to the medication therapy and the time until last escape medication is given

Study description

Background summary

A renal colic is an excruciating pain which is often difficult to control. Tailored analgesia in patients not responding to oral Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) is a therapeutic challenge. There is a variety of analgesic regimes worldwide. In the Netherlands these patients are admitted to the hospital and are traditionally treated with a continuous perfusion of butylscopolamine. However recently, the Dutch Association of Urology together with patient organisations produced a document on clinical knowledge gaps relevant for the daily urological practice. One of the knowledge gaps mentioned was the lack of scientific evidence for the effiency of butylscopolamine in renal colics. The Netherlands is one of few countries where butylscopolamine is widely used empirically to reduce renal colics.

Study objective

The purpose of this study is to analyse the effect on pain reduction of butylscopolamine in a continuous intravenous infusion compared to a placebo in patients with renal colics not responding to oral NSAIDs.

Study design

A double blind placebo controlled, multicenter, randomized clinical trial

Study burden and risks

Patients are asked to fill out a questionnary 5 times

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Legally capable and competent to understand the implications of participation in the study and signed informed consent
• Age 18 years or older
• presentation with renal colic confirmed by ultrasound or CT-scan, not responding to oral NSAIDs and therefore admitted to the urological ward for pain medication.

Exclusion criteria

• Pregnancy or lactation
• Known allergy to any of the products used
• Contra-indication for NSAIDs
• Diagnosis other than renal colic
• Patients presenting with a temperature > 38.5°C at time of inclusion or <24 hours ago
• Patients with antibiotic for UTI together with urolithiasis or urolithiasis with indication for drainage of the upper urinary tract
• Any of the following conditions:
- Megacolon
- Intestinal mechanical stenoses
- Myasthenia gravis
- Untreated narrow angle glaucoma
- Epilepsy
- Alcohol or drugs intoxication
- Creatinin clearance < 30 ml/min
- Atrial fibrillation with heart rate > 100/min
- Ischemic heart disease
- Heart failure
- Severe aortic valve stenosis

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:	Completed
Start date (anticipated):	13-01-2018
Enrollment:	128
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Buscopan 20mg/ml solution for injection
Generic name:	Hyoscine butylbromide
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Sodium Chloride 0.9%
Generic name:	Sodium Chloride 0.9%
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	11-08-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	27-10-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	14-05-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	01-03-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	EUCTR39.560.058.12-NL
CCMO	NL56469.098.17

Study results

Date completed:	07-11-2019
Results posted:	19-05-2020
Actual enrolment:	128

First publication

19-05-2020