A randomised controlled trial of a continuous butylscopolamine infusion versus a placebo infusion in patients with a renal colic not responding to oral NSAIDs

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29114

Source
NTR

Brief title
Buscopan

Health condition

Urolithiasis

Sponsors and support

Primary sponsor: Haga teaching hospital
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The primary outcome in this study is the amount of escape medication used during the 24-hour
period of observation, measured in units.

Secondary outcome

• Pain reduction in Numerice Rating Scale score (NRS score). NRS scores are documented at at 0 hours, 1 hours, 4 hours, 8 hours and 24 hours.
• Side effects of buscopan and side effects of the escape medication Extra medication needed to treat possible side effects of the study medication (nausea, vomiting)
• Interventions necessary because of ongoing pain
• Time until last escape medication is given

Study description

Background summary

Rationale: 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 formulated 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.
Objective The purpose of this study is to prove that treatment with placebo intravenously is noninferior
to treatment with butylscopolamine in a continuous intravenous infusion when treating patients with renal colics not responding to oral NSAIDs.
Study design: A double blind placebo controlled, multicenter, randomised controlled clinical trial
Study population: The patient population consists of adults presenting with a renal colic, diagnosed
by ultrasound or CT-scan, not responding to oral NSAIDs and therefore admitted to the urological
ward for pain medication.
Intervention: Patients are randomized in one of two study-arms. They will receive either

butylscopolamine in a continuous infusion or saline in a continuous infusion. Both groups have the
availability of piritramide injections as escape medication aiming for a score of 0 on NRS scale.
Main study parameters/endpoints: The primary endpoint is the amount of escape medication during
the 24-hour period of observation in units.
The secondary endpoints are pain reduction in Numerice Rating Scale score (NRS score), the side
effects of the different medications, rate of interventions and time until last need for escape medication.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients have to fill in a NRS score and a questionnaire about the side effects 5 times.
They will all have the possibility to use escape medication and will therefore be treated adequately
for their pain. The main risk is the possible need for more escape medication and the associated side
effects. All medications used are already registered and clinicaly widely used for this indication.

Study objective

Null hypothesis: placebo is non-inferior to continuous intravenous infusion with buscopan in terms of
amount of escape medication used in patients admitted for renal colic.

Study design

24 hours

Intervention

At the start all patients wil receive 1000 mg paracetamol 4 times daily and 50 mg Diclofenac 3 times
daily if they haven’t taken or received these earlier. Group A will be given butylscopolamine 100 mg
in 24 hours via an intravenous continuous infusion. Group B will receive saline in 24 hours via an
intravenous continuous infusion.
NRS scores are documented at at 0 hours, 1 hours, 4 hours, 8 hours and 24 hours. Escape medication
is used to maintain adequate pain relief. A pain score below 4 is accepted as adequate pain management. After 24 hours, the study period ends and giving standard of care is continued.

Contacts

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Eligibility criteria

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 type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-01-2018
Enrollment:	128
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	21-06-2019
Application type:	First submission

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
NTR-new	NL7819
Other	METC Leiden/The Hague : METC-nummer 17-081

Study results