The effect of tamsulosin on the spontaneous passage of bile stones

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Primary objective: 1. Determine difference in stone expulsion rate with -and without Tamsulosin Secondary objectives: 1. Time to stone expulsion2. Stone expulsion rate in patients with cholangitis with -and without Tamsulosin3. Adverse events 4....

Ethical review	Approved WMO
Status	Pending
Health condition type	Bile duct disorders
Study type	Interventional

Summary

ID

NL-OMON48799

Source
ToetsingOnline

Brief title
TASTE

Condition

- Bile duct disorders

Synonym
bilairy colic, choledocholithiasis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: Stichting Coolsingel

Intervention

Keyword: common bile duct, expulsion, stone, Tamsulosin

Outcome measures

Primary outcome

The main study endpoint will be to determine difference in stone expulsion rate with -and without Tamsulosin.

Secondary outcome

1. Time to stone expulsion. The amount of time from the moment of diagnosis until passage of the stone in to the duodenum, will be compared between the placebo and Tamsulosin group.

2. Stone expulsion rate in patients with cholangitis with -and without Tamsulosin (sub analysis). The rate of passage of biliary stones in to the duodenum will be compared between the placebo and Tamsulosin group.

3. Adverse events

4. Usage of morphine.

Study description

Background summary

Due to the rise in obesity the number of patients with biliary stones in the common bile duct (CBD) rises as well. Currently it is common practice to remove these biliary stones during an endoscopic retrograde cholangiography (ERC). In up to 22-54% of patients with biliary stones in the CBD, the stones spontaneously pass in to the duodenum. This patient group does not need an invasive procedure like ERC. Urologists successfully use tamsulosin, an α1-antagonist, to improve expulsion of ureteral stones. In vitro and in vivo studies show relaxation of the sphincter of Oddi and the smooth muscle tissue surrounding the CBD in cats, when an α-antagonist is administered. Human research shows similar findings. One study has shown α-antagonists to improve

the expulsion of biliary stones in the CBD. The hypotheses in this study is: use of Tamsulosin improves expulsion of biliary stones in the CBD.

Study objective

Primary objective:
1. Determine difference in stone expulsion rate with -and without Tamsulosin

Secondary objectives:
1. Time to stone expulsion
2. Stone expulsion rate in patients with cholangitis with -and without Tamsulosin
3. Adverse events
4. Usage of morphine

Study design

We are aiming for a single center double blind randomized controlled trial comparing use of Tamsulosin (intervention group) and placebo (control group) in patients with biliary stones in the CBD. The intervention group will receive Tamsulosin 0.4mg, to be taken once a day until endoscopic retrograde cholangiography (ERC) or objectivated stone passage during endoscopic ultrasound (EUS). The control group receives a placebo with similar features as Tamsulosin, to be taken once a day until ERC or objectivated stone passage during EUS as well. All patients with biliary stones on EUS will get a subsequent ERC, to remove remaining biliary stones. During ERC the endoscopist will look for signs suggesting spontaneous passage of biliary stones. Such as, the aspect of the duodenal papilla, presence of stones on cholangiogram, passage of stones in to the duodenum during the ERC procedure, this will be reported in all ERC reports.

This study does not delay the routine interventions of management of CBD stones. The clinician and availability of ERC will determine the time to ERC. For example, patients with cholangitis will be more likely to get an early ERC compared to patients without cholangitis.

One of the following criteria must be present to state the biliary stone has passed in to the duodenum:
- Absence of colic pain and a 50% decrease in liver test abnormalities
- Absence of biliary stone(s) during EUS/ERC

In order to reduce bias both patient and clinician will be blinded. This is done by the pharmacy department where Tamsulosin and placebo will be stored and from where it will be distributed. Before the start of the study a list with inclusion number and either Tamsulosin or placebo will be made with a randomization program. The pharmacy department will be in possession of this

list in order to be able to distribute the right medication.
The study will be a single center study taking place in the *Franciscus Gasthuis & Vlietland* in Rotterdam.

Intervention

The intervention group will receive Tamsulosin (Tamsulijn) 0.4mg once daily until either ERC or objectivation of stone passage with endoscopic ultrasound.
The control group will receive a placebo once daily until either ERC or objectivation of stone passage with endoscopic ultrasound.

Use of co-intervention

The use of analgesics according the WHO pain ladder is permitted. Use of spasmolytics for example scopolaminebutyl (buscopan) is prohibited, since these substances could influence study results.

Study burden and risks

Only participants randomized to the intervention group have the limited risk of experiencing mild side effects of Tamsulosin. The most common side effects (1-10%) are: dizziness, orthostatic hypotension, problems ejaculating e.g. anejaculation or retrograde ejaculation. No other risks are expected.

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

- Choledocholithiasis (definition below)
- Age >=18 years
- Written informed consent

Definition of choledocholithiasis, at least 2 of the following criteria:
- Choledocholithiasis (proven on CT/US/MR)
- Colic pain
- Bilirubin >= 40 µmol/L OR ALAT >= 2 times upper limit

Exclusion criteria

- Patients already using Tamsulosin
- Patients participating in other trials
- Pregnancy (description procedure below)
- Patients presenting with a pancreatitis
- Patients with a previous papillotomy

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-03-2020
Enrollment:	350
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Generic name:	tamsulosin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	03-07-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-02-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-12-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2018-001380-23-NL
CCMO	NL65686.078.19