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Comparison of 60-seconds versus 30-seconds endoscopic balloon dilation after endoscopic sphincterotomy for the management of bile duct stones

Submission date
21/05/2012

Recruitment status
No longer recruiting

Registration date
09/07/2012

Overall study status
Completed

Last Edited
22/09/2016

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Bile stones are small stones that form in the gallbladder and become lodged in the bile duct, causing pain. Endoscopic sphincterotomy followed by balloon dilation is a promising treatment for patients with large stones, multiple stones, and narrowing or twisting of the bile duct. Endoscopic sphincterotomy is an operation that uses a catheter (tube) and a wire to remove the bile stones. Balloon dilation uses a catheter with an inflatable balloon to widen the bile duct. However, there are no data on the ideal duration of balloon dilation. The aim of this study is to compare the effectiveness and complications of 30 or 60 seconds of balloon dilation after endoscopic sphincterotomy.

Who can participate?
Patients with bile stones that are 12 mm or wider that cannot be extracted using a standard balloon catheter in the bile duct

What does the study involve?
Participants are randomly allocated to undergo endoscopic sphincterotomy followed by either 30 or 60 seconds of balloon dilation. The effectiveness of the operation and complications are compared between the two groups.

What are the possible benefits and risks of participating?
No benefits are expected for patients participating in the study. The risks include pancreatitis (inflammation of the pancreas) and bleeding.

Where is the study run from?
Venizelio Hospital (Greece)

When is the study starting and how long is it expected to run for?
September 2009 to October 2011

Who is funding the study?
Venizelio Hospital (Greece)

Who is the main contact?
Dr Gregorios Paspatis

Contact information

Type(s)
Scientific

Contact name
Dr Gregorios Paspatis

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol number from ethical committee: 5334

Study information

Scientific Title
A randomized comparison of 60-seconds versus 30-seconds endoscopic balloon dilation after endoscopic sphincterotomy for the management of bile duct stones

Study objectives
We assumed that increase in duration of balloon dilation from 30 to 60 sec offers an increase from 70% to 90% clearance of the bile ducts between the two groups at the 5% level of significance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomized study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Bile duct stones

Interventions
Full length endoscopic sphincterotomy (ES) followed by 60-seconds versus 30-seconds balloon dilation (BD) for cases with large unretrieved stones, multiple stones and tapering or tortuosity of distal common bile duct.

Intervention Type
Procedure/Surgery

Primary outcome measure
Our data showed that 30-sec BD after ES for the management of bile duct stones was equally effective as 60-sec. Therefore, there is no need to exceed 30 seconds when removing stones from bile ducts with balloon dilation.

Secondary outcome measures
Study showed that the rate of post-procedure complications was not different between the two groups

Overall study start date
01/09/2009

Completion date
01/10/2011

Eligibility

Key inclusion criteria
Patients with bile duct stones≥ 12mm (transverse diameter of the largest stone) that could not be extracted using a standard balloon catheter in the common bile duct

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
124 patients

Key exclusion criteria
1. Need for needle knife pre-cutting
2. Selective bile duct cannulation achieved after more than two accidental pancretograms or more than two insertions of the guidewire in the pancreatic duct
3. Cases with bleeding tendency (taking anticoagulant therapy, platelet count of less than 100.000/mm3, or prothrombin time more than 30% above the control
4. Billroth II or Roux-en Y reconstruction
5. Bile duct stones with diameter ≥20mm
6. Strictures
7. Patients undergoing anticoagulant or antiplatelet therapy for non-critical problems, such as cardiovascular and cerebral disorders, were instructed to discontinue the use of these types of medication at least 7 days before the endoscopic procedure

Date of first enrolment
01/09/2009

Date of final enrolment
01/10/2011

Locations

Countries of recruitment
Greece

Study participating centre
Leoforos Knossou
Heraklion
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71409

Sponsor information

Organisation

Venizelio Hospital (Greece)

Sponsor details
Leoforos Knossou
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/043889z90

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Venizelio Hospital (Greece)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration