

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

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Registration date 09/07/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/09/2016	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomized study

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

Completion date

01/10/2011

Eligibility**Key inclusion criteria**

Patients with bile duct stones \geq 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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Need for needle knife pre-cutting
2. Selective bile duct cannulation achieved after more than two accidental pancreatograms 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 ≥ 20 mm
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

Greece

71409

Sponsor information

Organisation

Venizelio Hospital (Greece)

ROR

<https://ror.org/043889z90>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Venizelio Hospital (Greece)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration