

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

<b>Submission date</b> 21/05/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/07/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 22/09/2016	<b>Condition category</b> 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

**Contact details**  
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Greece  
71409

## 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  $\geq$  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

**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/mm<sup>3</sup>, or prothrombin time more than 30% above the control
4. Billroth II or Roux-en Y reconstruction
5. Bile duct stones with diameter  $\geq 20$ 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)

**Sponsor details**

Leoforos Knossou  
P.O. BOX 1044  
Heraklion  
Greece  
71409

**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