

# Assessment of strangulated content of inguinal hernia spontaneously reduced during induction to anaesthesia through internal inguinal ring laparoscopy

<b>Submission date</b> 09/10/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/10/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/07/2021	<b>Condition category</b> Digestive System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

## Study information

### Scientific Title

Assessment of strangulated content of inguinal hernia spontaneously reduced during induction to anaesthesia through internal inguinal ring laparoscopy

**Study objectives**

This study aims to evaluate the results of hernia sac laparoscopy in cases of spontaneously reduced strangulated hernia content.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval received from the Ethical and Scientific Committee of Red Cross Hospital "Korgialenio-Benakio" on the 31st January 2003.

**Study design**

Prospective randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Strangulated hernia

**Interventions**

All patients undergoing an emergency operation for incarcerated inguinal hernia are candidates. In case the hernia contents had spontaneously reduced through the internal inguinal ring definitely before the assessment of the vitality of the contents, patient is randomly assigned in one of two groups:

Group A: patients addressed with the addition of laparoscopy

Group B: patients managed with the regular surgical practice

Randomisation was executed by opening of a sealed envelope. In group A a 10-mm trocar was inserted through the internal inguinal ring and a tight purse-string suture was placed on the hernia sac. A 10-mm laparoscope was inserted to visualise the incarcerated content and assess its viability). In group B, if dark or haemorrhagic fluid was eminent originating from the peritoneal cavity through the open hernia sac, the decision was left to the surgeon for an investigatory midline laparotomy.

The duration of the intervention will continue until 26 patients are enrolled in both groups and follow up will occur one month later after the last patient has been operated (with the present rates of enrolment this may be up to 02/2010).

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

1. Major morbidity, measured within 30 days postoperatively
2. Mortality, measured within 30 days postoperatively

### **Key secondary outcome(s)**

1. Operative time, measured after patient discharge
2. Hours of hospitalisation, measured after patient discharge
3. Days of return to full ordinary and professional activities, measured after the 2 months postoperative follow up

### **Completion date**

01/02/2010

## **Eligibility**

### **Key inclusion criteria**

Patients aged 15 - 90 years undergoing an emergency operation due to incarcerated hernia with spontaneous hernia contents reduction before assessment of the strangulated content.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Not Specified

### **Sex**

All

### **Total final enrolment**

41

### **Key exclusion criteria**

1. Poor physical condition not suitable for laparoscopy
2. American Society of Anaesthesiology (ASA) status more than three
3. Denied the randomisation procedure
4. Sepsis at admission
5. A proved direct incarcerated hernia during exploration
6. Incarcerated hernia contents remained in situ (did not reduce spontaneously) until assessment

### **Date of first enrolment**

01/02/2003

### **Date of final enrolment**

01/02/2010

## **Locations**

### **Countries of recruitment**

Greece

**Study participating centre**  
**11 Mantzarou Street**  
Athens  
Greece  
15451

## Sponsor information

**Organisation**  
Korgialenio Benakio Red Cross Hospital (Greece)

**ROR**  
<https://ror.org/00nnh8h94>

## Funder(s)

**Funder type**  
Other

**Funder Name**  
Investigator initiated and funded (Greece)

## Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/04/2009	15/07/2021	Yes	No