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

Submission date
09/10/2007

Recruitment status
No longer recruiting

Registration date
19/10/2007

Overall study status
Completed

Last Edited
15/07/2021

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr George Sgourakis

Contact details
11 Mantzarou Street
Neo Psychiko
Athens
Greece
15451
-
ggsgourakis@yahoo.gr

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/02/2003

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

Age group
Not Specified

Sex
Both

Target number of participants
26 patients per treatment arm (total = 52)

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)

Sponsor details
2nd Surgical Department
1 Erythrou Stavrou Kai Athanasakh Street
Athens
Greece
11526
-
karaliotas@korgialenio-benakio.gr

Sponsor type
Hospital/treatment centre

Website

http://www.Korgialenio-Benakio.gr/

ROR
https://ror.org/00nnh8h94

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/04/2009	15/07/2021	Yes	No