

Laparoscopic Excision versus Open Appendectomy multicentre Randomised, Double blind, controlled trial

Submission date 04/08/2005	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/04/2009	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Multicentre randomised, double-blind, controlled trial of laparoscopic versus open surgery for suspected appendicitis in adults

Acronym

LEONARDO

Study objectives

To compare the therapeutic effects of laparoscopic appendectomy (LA) and conventional open appendectomy (OA) in the treatment of suspected acute appendicitis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

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

Suspected acute appendicitis

Interventions

Laparoscopic appendectomy (LA) versus conventional open appendectomy (OA)

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Post-operative pain (cm visual analogue scale [VAS], number of analgesic doses)

Secondary outcome measures

1. Wound infections (rate)
2. Intra-abdominal abscesses (rate)
3. Duration of operation (minutes), defined as operating time, anaesthesia time, or operating room time
4. Length of hospital stay (days/hours)
5. Return to normal activity (days), subdivided in: time until return to full activity, work, or sport
6. Return of bowel function (hours), subdivided in: time until first stool, introduction of liquid or solid diet
7. Cosmesis (cm VAS, number of analgesic doses)

Overall study start date

01/01/2006

Completion date

31/12/2007

Eligibility**Key inclusion criteria**

Adult (from 18 years old) patients with symptoms and signs of acute appendicitis, any gender.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

386 (193 patients for each group)

Key exclusion criteria

1. Refusing of informed consent
2. Any condition preventing a correct evaluation of pain (non-cooperative patient, blind patient)
3. Patients with contraindication to be operated with either LA (to be stated), or OA (to be stated) will be excluded from the study
4. American Society of Anaesthesiologists (ASA) grade IV or V
5. Not fluent Italian speakers

Date of first enrolment

01/01/2006

Date of final enrolment

31/12/2007

Locations**Countries of recruitment**

Italy

Study participating centre**Unit of Emergency Surgery**

Bologna

Italy

40138

Sponsor information**Organisation**

Sant'Orsola-Malpighi University Hospital Bologna (Italy)

Sponsor details

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cometico@aosp.bo.it

Sponsor type

Hospital/treatment centre

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Sant'Orsola-Malpighi University Hospital of Bologna (Azienda Ospedaliero-Universitaria di Bologna, Policlinico Sant'Orsola-Malpighi) (Italy)

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