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Laparoscopic Excision versus OpeN Appendectomy multicentre Randomised, DOuble blind, controlled trial

Submission date 04/08/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 05/10/2005	**Overall study status** Completed	
Last Edited 27/04/2009	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

118/2005/U

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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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