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Laparoscopic versus open appendectomy

Submission date
04/12/2011

Recruitment status
No longer recruiting

Registration date
18/01/2012

Overall study status
Completed

Last Edited
28/10/2014

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Appendicitis is a painful swelling of the appendix, a finger-like pouch connected to the large intestine. It is traditionally classified as uncomplicated or complicated, and is treated by removal of the appendix, known as an appendectomy or appendicectomy, which is the most commonly performed surgical procedure. Appendicectomy can be performed by one of two methods. Laparoscopic appendicectomy (LA) involves making several small cuts in your abdomen through which special surgical instruments are inserted. Open appendicectomy (OA) involves making a single larger cut in the abdomen. Currently the Department of Surgery at Chris Hani Baragwanath Hospital, Johannesburg, South Africa, practises both OA and LA in the treatment of perforated appendicitis (burst appendix). To date there have been no studies comparing outcomes between OA and LA in perforated appendicitis. The aim of this study is to compare the intra-operative duration, the rate of wound sepsis, the rate of relook, the length of hospital stay and the rate of re-admissions between the OA and LA groups. Additionally we aim to look at whether the duration of the symptoms has any effect on the outcome between the two procedures.

Who can participate?
Patients presenting with acute abdomens suspected to be caused by perforated appendicitis at Chris Hani Baragwanath Hospital.

What does the study involve?
Participants will be randomly allocated to undergo either OA or LA. A team of senior surgeons capable of doing both OA and LA will perform the surgery. Surgeons will perform standardized procedures in both subgroups as per current clinical guidelines.

What are the possible benefits and risks of participating?
As this study will be comparing the outcomes of two different emergency surgical procedures, patients will be subjected to the risks which are associated with the surgical procedures. It must be noted that all patients recruited into the study need emergency surgery and thus inclusion in the study per se adds no additional risk factors to patients.

Where is the study run from?
Chris Hani Baragwanath Hospital, Johannesburg, South Africa.

When is the study starting and how long is it expected to run for?
The study began in December 2011 and ran for about 6 months.

Who is funding the study?
There is no sponsor for the above trial. Should any minor costs be incurred they will be funded by the Department of Surgery, University of Witwatersrand, Johannesburg, South Africa.

Who is the main contact?
Dr John Thomson
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Laparoscopic versus open procedure for perforated appendix: a randomized controlled trial

Study objectives
In the treatment of perforated appendicitis, laparoscopic appendicetomy is associated with lower morbidity than open appendicetomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Research Medical Ethics Committee, University of the Witwatersrand, Johannesburg, 27 /11/2011, ref: M110730

Study design

Prospective single-centre randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Open appendicetomy (OA) versus laparoscopic appendicetomy (LA)

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Intra-operative duration
2. The rate of wound sepsis
3. The rate of re-look (the number of re-operations required as a result of the appendicitis or subsequent sequel of the appendicitis)
4. The length of hospital stay
5. The rate of re-admissions

Key secondary outcome(s))
Whether the duration of the symptoms has any effect on the outcome between the two procedures

Completion date
31/05/2012

Eligibility

Key inclusion criteria
All potential patients presenting with appendicitis at Chris Hani Baragwanath Hospital, Johannesburg, South Africa

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients less than 12 years of age
2. Those who have undergone previous abdominal surgery
3. Pregnant patients

Date of first enrolment
05/12/2011

Date of final enrolment
31/05/2012

Locations

Countries of recruitment
South Africa

Study participating centre
2 Edward Drive
Johannesburg
South Africa
1609

Sponsor information

Organisation
University of Witwatersrand (South Africa)

ROR
https://ror.org/03rp50x72

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Surgery, University of Witwatersrand (South Africa)

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?
Results article	results	01/07/2015		Yes	No