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Laparoscopic versus open appendectomy

Submission date	Recruitment status	[_] Prospectively registered
04/12/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/01/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/10/2014	Digestive System	

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
Dr John Thomson

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1609

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the conatct details below to request a patient information sheet

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

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

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
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

Secondary outcome measures
Whether the duration of the symptoms has any effect on the outcome between the two procedures

Overall study start date
05/12/2011

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

Age group
Adult

Sex
Both

Target number of participants
100 patients

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)

Sponsor details
c/o Prof Thifheli Luvhengo
Department of Surgery
Baragwanath Hospital
R68 Old Potchefstroom Road
PO Bertsham
Johannesburg
South Africa
2013

Sponsor type
Hospital/treatment centre

Website
http://www.wits.ac.za/

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

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	results	01/07/2015	Yes	No