

Laparoscopic versus open appendectomy

Submission date 04/12/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 18/01/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 28/10/2014	Condition category Digestive System	☐ 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

Dr John Thomson

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Additional identifiers

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

Primary study design

Interventional

Study design

Prospective single-centre randomized controlled trial

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