

# Conventional versus keyhole removal of appendix in Nigerian patients

<b>Submission date</b> 07/09/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/11/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/11/2022	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Background and study aims

We are not sure how much money patients spend on different kinds of operation. This makes it difficult to advise the government and policy makers on investment and spending for healthcare. This study will calculate the amount spent by patients on two types of operation to help with planning for healthcare financing

Who can participate?

Patients who are undergoing operations for removal of the appendix

What does the study involve?

Patients will have their operations done in the usual fashion decided by their surgeon and their hospital. Data regarding their operation, recovery and recuperation will be collected without disclosing the patient's identity. The researchers will also ask specific questions regarding costs incurred by patients. Patients will be followed up till 30 days after the operation.

What are the possible benefits and risks of participating?

The findings will be communicated to surgeons, hospitals, government and policy makers, not only in Nigeria but across the world. This will influence the policies on surgical operations in Nigeria and other countries. Apart from the time to answer the questions, the researchers will not require anything else from participants. Participation in this study will be at no risk to the patient

Where is the study run from?

Obafemi Awolowo University (Nigeria)

When is the study starting and how long is it expected to run for?

January 2022 to January 2024

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Adewale Adisa, ao.adisa@oauife.edu.ng

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Adewale Adisa

### ORCID ID

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## Additional identifiers

### Protocol serial number

NHREC/01/01/2007- 11/03/2022

## Study information

### Scientific Title

Outcomes-focused comparison of laparoscopic and open appendectomy in Nigeria: a multicenter cohort study

### Acronym

LOAN

### Study objectives

There are no significant differences in the outcome of patients with appendectomy operated either by the laparoscopic or open approach across many Nigerian hospitals

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 03/06/2022, National Health Research Ethics Committee of Nigeria (Department of Health Planning, Research & Statistics, Federal Ministry of Health, 11th Floor, Federal Secretariat Complex Phase III, Ahmadu Bello Way, Abuja, Nigeria; +234 (0)9 523 8367; chairman@nhrec.net, secretary@nhrec.net, deskofficer@nhrec.net), ref: NHREC/01/01/2007-03/06/2022

## **Study design**

Outcomes-focused multicenter cohort study

## **Primary study design**

Observational

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Uncomplicated acute appendicitis

## **Interventions**

All patients scheduled for appendectomy who consent to the study will be recruited. One arm is treated by laparoscopic appendectomy while the other arm is treated by open appendectomy. They will have their operations done in the usual fashion decided by their surgeon and their hospital. Data regarding their operation, recovery and recuperation will be prospectively collected. Patients will be followed up till 30 days after operation.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Complications measured using the Clavien-Dindo scale at 30 days after the operation

## **Key secondary outcome(s)**

1. Postoperative length of stay measured as the total number of days spent from the conclusion of operation calculated at the time decision to discharge home is made by a surgeon of sufficient authority
2. Return to normal activities defined as the first-day patients went to work, school, or engaged in the full retinue of premorbid activities (in its broadest sense) after discharge from the hospital
3. Overall cost of operation in Nigerian Naira calculated and reported by the patient, parents, or guardian on day 30 after the operation

## **Completion date**

31/01/2024

## **Eligibility**

### **Key inclusion criteria**

1. All consenting adults and children of all ages with clinical diagnoses of uncomplicated acute appendicitis. Both elective and emergency appendectomies will be recruited.
2. Patients must provide written informed consent for the operation as per the hospital protocol. Consent for this study will largely be for the inclusion of the patients' data in the study

as well as for follow-up for a minimum of 30 days postoperatively. This consent can be obtained in written or verbal forms. Patients' right to decline inclusion and or to withdraw from the study at any point must be ensured and this should not interfere in any way with their surgical care.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

All

**Sex**

All

**Key exclusion criteria**

Complicated acute appendicitis

**Date of first enrolment**

01/07/2022

**Date of final enrolment**

31/12/2023

**Locations****Countries of recruitment**

Nigeria

**Study participating centre**

Obafemi Awolowo University Teaching Hospitals Complex

Ile-Ife

Nigeria

220005

**Study participating centre**

University of Lagos

Idi-Araba

Lagos

Nigeria

100254

**Study participating centre**

**University of Benin Teaching Hospital**  
Benin City  
Nigeria  
300001

**Study participating centre**  
**National Hospital**  
Abuja  
Nigeria  
900211

**Study participating centre**  
**Federal Medical Center**  
Lokoja  
Nigeria  
260101

**Study participating centre**  
**Olabisi Onabanjo University Teaching Hospital**  
Sagamu  
Nigeria  
110271

**Study participating centre**  
**University of Ilorin Teaching Hospital**  
Ilorin  
Nigeria  
240101

## **Sponsor information**

**Organisation**  
Obafemi Awolowo University

**ROR**  
<https://ror.org/04snhqa82>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Individual participant data (IPD) sharing plan

IPD will be saved on a personal computer dedicated to the trial and will not be publicly available. Data will only be available to hospital leads and data scientists. Each participating center is currently storing data in an Excel spreadsheet. The researchers however desire to keep their records on the RedCap site after securing funding for the study.

## IPD sharing plan summary

Stored in non-publicly available repository, Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			21/09/2022	No	Yes