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Clinical Officer Surgical Training in Africa (COST-Africa)

Submission date
07/01/2014

Recruitment status
No longer recruiting

Registration date
27/02/2014

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Emergencies related to childbirth and distress represent a major and neglected part of Africas burden of disease. This is very common in district hospitals in Malawi and Zambia and other similar countries in Sub-Saharan Africa. These places lack trained staff to manage the burden of disease leading to surgery. This study (COST-Africa) proposes to show the impact, cost-effectiveness and possibility of providing surgical training to clinical officers. Surgical training of clinical officers has been tried and apparently works well in several African countries. However, it has never been carefully evaluated. A Bachelor of Science (BSc) in General Surgery has been established in Malawi for clinical officers and an improved surgical training programme has been designed for clinical officers undergoing medical licentiate training in Zambia, with support from COST-Africa. The study is designed to establish that non-physician clinicians can provide essential surgical care at district hospitals, safely, effectively and within the resource constraints of African countries. The study will develop guidelines for national Clinical Officer surgical training programmes across Africa.

Who can participate?
Participants will include the district hospitals, clinical officers and patients in the hospitals who undergo surgery.

What does the study involve?
The study evaluates two different models for training clinical officers to perform general surgery: an in-service training model in Malawi and a centralised training model in Zambia. Each of these models includes on-the-job technical support and coaching involving senior surgeon-supervisors who the clinical officers can consult for advice. For a period of 18 months the selected clinical officers will be placed at treatment hospitals where they will perform general surgery with periodic supervisory visits from trained surgeons. The study will be assessing the outcomes of surgery performed by the trained clinical officers in these hospitals. The results in these hospitals will be compared with results of surgery in control hospitals without trained clinical officers. During the study period the control hospitals will continue with their normal patient care procedures.

What are the possible benefits and risks of participating?
The study will help increase the volume and types of surgeries performed and improve surgical outcomes. This should help reduce referrals of patients requiring surgery to central hospitals. We do not expect any harm to be experienced at the hospital level. For clinical officers, they will improve their skills in performing surgery through mentored training by experienced surgeons, which will continue to more attractive career paths and retention within the health system. We do not expect any harm to clinical officers. For patients undergoing surgery we do not expect that their participation in the project will bring them any harm, as decisions on what kind of surgery is undertaken will be subject to the supervision and guidance of trained surgeons. Surgery will only be undertaken where it is likely to bring benefits.

Where is the study run from?
The study will be conducted at district hospitals in Malawi and Zambia (8 in Malawi and 15 in Zambia).

When is the study starting and how long is it expected to run for?
The study started in March 2011 and will last 60 months.

Who is funding the study?
European Union (EU).

Who is the main contact?
Coordinator: Professor Ruairi Brugha (Ireland), rbrugha@rcsi.ie
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Study website
http://www.costafrica.eu

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
FP7-AFRICA-2010, no: 266417

Study information

Scientific Title
Clinical Officer surgical training in Africa (COST-Africa): a cluster randomised controlled trial

Acronym
COST-Africa

Study objectives
Clinical Officers (COs) in Malawi and Medical Licentiates (MLs) in Zambia are trained non-physician clinicians (NPCs). The study proposes that providing surgical training to NPCs in Africa will enable district hospitals to provide patients with cost-effective and safe surgical care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Committee of the Royal College of Surgeons in Ireland, 30th April 2012, ref: REC727
2. The University of Zambia Biomedical Research Ethics Committee, Zambia, 29th May 2012, ref: 018-03-12
3. University of Malawi, College of Medicine Research Ethics Committee (COMREC), Malawi, 31st July 2012, ref: P.03/12/1188.

Study design
Cluster randomised 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 contact traceymccauley@rcsi.ie to request a patient information sheet

Health condition(s) or problem(s) studied
Diseases / conditions amenable to surgery

Interventions
Random allocation of district hospitals to intervention and control arms within pairs of similar (matched) district hospitals in Malawi and Zambia.

1. Intervention arm: the selected clinical officers will be placed at treatment hospitals (8 in Malawi and 15 in Zambia) where they will perform general surgery, with periodic supervisory visits from trained surgeons.

2. Control arm: hospitals without trained clinical officers. The study will measure outcomes at different levels: the graduate clinical officers, the hospitals, surgical patients and their families. During the study period the control hospitals will continue with their normal patient care procedures.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Increase in the types and volume (numbers) of general surgical procedures at the interventions hospitals

Secondary outcome measures
1 Improved competence of COs/MLs to undertake general surgery, measured in terms of enhancements in:
1.1. Their surgical skills
1.2. Clinical management of patients
1.3. Implementation of clinical best practice protocols
1.4. Health care of patients
2. Change in rates of referral for general surgical procedures.
3. Change in morbidity and mortality from surgical conditions, improved quality of life
4. Reduced expenditure, both for hospitals providing surgery and patients undergoing surgery
5. Cost effectiveness in delivering general surgery by COs/MLs at the district level

Overall study start date
01/04/2011

Completion date
30/03/2016

Eligibility

Key inclusion criteria

District hospitals with the infrastructural capacity to delivery surgery

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
All suitable patients undergoing surgical procedures at the 8 intervention hospitals in Malawi and in at least 10 intervention hospitals in Zambia

Total final enrolment
16

Key exclusion criteria
Children under five years of age attending district hospitals

Date of first enrolment
01/04/2011

Date of final enrolment
30/03/2016

Locations

Countries of recruitment
Ireland

Malawi

Zambia

Study participating centre
Royal College of Surgeons in Ireland (RCSI)
Dublin
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Sponsor information

Organisation

Royal College of Surgeons in Ireland (Ireland)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/01hxy9878

Funder(s)

Funder type
Government

Funder Name
European Union (EU) - 7th Framework Programme for Research and Technological Development (FP7) Grant, Ref: FP7-AFRICA-2010, grant agreement no: 266417

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	22/07/2019	17/12/2020	Yes	No