ISRCTN12353489 https://doi.org/10.1186/ISRCTN12353489

Assessing the need for surgical treatments in Sierra Leone

Submission date 11/10/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/10/2019	**Overall study status** Completed	
Last Edited 18/08/2025	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims

The need for surgical procedures is increasing, especially in developing countries where there is generally more need than availability. Research on the need for different types of surgery is needed to raise awareness of the medical need of people in these countries, to convince donors of the number of people with conditions that can be treated using surgery and to provide policy makers with the data needed to plan interventions. This study aims to investigate the need for surgery in Sierra Leone.

The researchers will conduct a survey on the numbers and types of surgeries needed across Sierra Leone. There are six parts to the study. The first is to repeat the Surgeon Over Seas Surgical Assessment Survey (SOSAS) from 2012, which was piloted in Sierra Leone. The original SOSAS study has already been performed in several other African and Asian countries, but has never been conducted twice in the same country. This will help us to see the differences in 7 years' time. Secondly, they aim to under stand how common lower urinary tract symptoms (LUTS) are among men and boys aged 12 years or older, including an evaluation of health-seeking behaviour (what people do to try to resolve their symptoms). In addition, the researchers aim to study groin hernia and associated health-seeking behaviour and wounds and associated health-seeking behaviour. The survey will also investigate the need for surgeries related to women's health and childbirth, including comparing the health of mothers and newborns before, during and after the Ebola outbreak in Sierra Leone. Lastly, the researchers aim to investigate the numbers of surgical procedures performed per year and understand whether the proportion performed under the country's health service or paid for privately.

Who can participate?

Any person living in a household in the areas of Sierra Leone selected for the survey.

What does the study involve?

The researchers will go to randomly selected areas of the country and will visit people in their homes. They will conduct interviews with a representative of the household and two people from the household who have been selected randomly by rolling a dice. Depending on whether the selected people are in certain groups (for example, boys or men aged over 12 years), they might be asked additional questions from the survey.

What are the possible benefits and risks of participating?
There is no treatment in this study. It only involves interviews and limited physical examinations, therefore there are no risks expected. People will be asked questions about times when they have been unwell and some people might find this distressing.
Benefits will be mostly long-term. The information gathered will help to improve access to surgical treatment in Sierra Leone.

Where is the study run from?
Masanga Medical Research Unit (Sierra Leone)

When is the study starting and how long is it expected to run for?
September 2018 to December 2019

Who is funding the study?
CapaCare (Norway), Masanga Medical Research Unit (Sierra Leone) and Statistics Sierra Leone (Sierra Leone)

Who is the main contact?
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Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PRESSCO-SL

Study information

Scientific Title
Prevalence Study on Surgical Conditions 2019 in Sierra Leone: PRESSCO-SL.

Acronym
PRESSCO-SL 2019

Study objectives

The need for surgical care is increasing, particularly in low- and lower middle-income countries where the burden of surgical conditions by far outweighs its treatment capacity. Knowledge on the prevalence of health conditions is needed to raise awareness of the medical need of populations, to convince donors of the magnitude of treatable conditions and to provide policy makers and ministries of health with the requisite data needed to plan interventions. To address these deficiencies for surgical conditions in Sierra Leone, community-level research to quantify the surgical need of the population is needed.

The purpose of this study is to assess the prevalence of surgical conditions in Sierra Leone. The study has six arms, which are interlinked:
1. Repeat the Surgeon Over Seas Surgical Assessment Survey (SOSAS) from 2012, which was piloted in Sierra Leone. The original SOSAS study has already been performed in several other African and Asian countries, but never before conducted twice in the same country.
2. Establish the prevalence of lower urinary tract symptoms (LUTS) among men 12 years or older, including an evaluation of health-seeking behaviour.
3. Establish the prevalence and incidence of groin hernia and health-seeking behaviour.
4. Establish the prevalence of wounds in Sierra Leone and health-seeking behaviour.
5. Establish the need for surgical female and obstetrical care in Sierra Leone, describe maternal and neonatal outcomes and their development in the pre-, during and post- Ebola time frame.
6. Establish the rates of surgical procedures performed per year and determine contributions of the public and private sector.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 12/11/2019:
1. Approved 03/10/2019, Office of the Sierra Leone Ethics and Scientific Review Committee ([SLERC], Directorate of Training and Research, Ministry of Health and Sanitation, 5th Floor, Youyi Building, Brookfields, Freetown; no telephone number; efoday@health.gov.sl), ref: none
2. Approved 28/10/2019, Regional Committee for Medical and Health Research Ethics, Central Norway (post@helseforskning.etikkom.no), ref: 31932

Previous ethics approval:
1. Approved 03/10/2019, Office of the Sierra Leone Ethics and Scientific Review Committee ([SLERC], Directorate of Training and Research, Ministry of Health and Sanitation, 5th Floor, Youyi Building, Brookfields, Freetown; no telephone number; efoday@health.gov.sl), ref: none
2. Pending, REC North - Secretariat (Nordland, Troms and Finnmark) (UiT Norges Arktiske Universitet, Postboks 6050, Langnes, 9037 Tromsø, Norway; +47 77 64 61 40; rek-nord@asp.uit.no)

Study design
Cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)

Home

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Need for surgery in Sierra Leone

Interventions
The household will be selected from the randomly selected enumeration areas. In the household the head of household will be informed about the study and informed consent will be asked and written consent obtained if applicable. The first part of the questionnaire (Parts A to D) will be taken if informed consent is given from the household representative. Parts E to N from the questionnaire are answered by two randomly selected household members. They will be asked for separate informed consent. It is estimated that 1 h will be needed for interview time per randomly selected person. They will be asked questions about health problems they have had and the treatment they received. If specific conditions are identified, there is a referral and transport protocol for the participants.

If one of the selected household members is under the age of 12 years, that person needs a chaperone to assist. This can be any of the present and available household members over the age of 18 years.

Intervention Type
Other

Primary outcome measure
SOSAS Repeat sub-study:
1. Demographic data including age, gender, level of education, occupation and ethnic background
2. Medical information, including health status, medical history, current complaints and clinical symptoms, complete head-to-toe verbal examination, health seeking behaviour, pregnancy history

Lower Urinary Tract Syndrome (LUTS) sub-study:
3. Medical information, including medical history, current complaints and clinical symptoms, health-seeking behaviour, outcome of Uflow meter

Groin Hernia sub-study:
4. Medical information, including medical history, current complaints and clinical symptoms, health-seeking behaviour, findings of physical examination

Wounds sub-study:
5. Medical information, including medical history, lifestyle, current illnesses and medication, clinical symptoms, health seeking behaviour, photograph of wound

Women's Health sub-study:
6. Medical information, including medical history, current complaints and clinical symptoms, health-seeking behaviour, family planning, pregnancy history, perinatal death, symphyseal-fundal height measured with tape measure

Surgical Volume sub-study:
7. Medical information, including medical history of deceased household members, medical history, visits to health care facilities in the past, health-seeking behaviour

Secondary outcome measures
SOSAS Repeat sub-study:
Demographic data including age, gender, level of education, occupation and ethnic background

Overall study start date
01/09/2018

Completion date
20/12/2019

Eligibility

Key inclusion criteria
SOSAS Repeat sub-study:
Two randomly selected household individuals who give informed consent

Lower Urinary Tract Syndrome (LUTS) sub-study:
Men and boys aged >12 years among the two randomly selected household individuals

Groin Hernia sub-study:
Two randomly selected household individuals

Wounds sub-study:
Two randomly selected household individuals

Women's Health sub-study:
Females aged 12-50 years among the two randomly selected household individuals

Surgical Volume sub-study:
All household members who have had a surgical procedure in past year

Participant type(s)
Mixed

Age group
All

Sex
Both

Target number of participants

1873 household representatives (1873 households) for first part of the survey; 3746 randomly assigned household members for second part of the survey.

Total final enrolment
3618

Key exclusion criteria
1. No informed consent given
2. Does not meet inclusion criteria of sub-study

Date of first enrolment
16/10/2019

Date of final enrolment
07/03/2020

Locations

Countries of recruitment
Sierra Leone

Study participating centre
Masanga Medical Research Unit
Masanga Hospital,
Masanga, Tonkolili district
Masanga
Sierra Leone
-

Sponsor information

Organisation
CapaCare

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Sponsor type
Charity

Website
https://capacare.org

Organisation
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Sponsor type
Hospital/treatment centre

Website
http://masangahospital.org

Funder(s)

Funder type
Charity

Funder Name
CapaCare

Funder Name
Masanga Medical Research Unit

Funder Name
Statistics Sierra Leone

Results and Publications

Publication and dissemination plan
All the six arms have the aim to publish their results in appropriate journals.

Intention to publish date
01/04/2020

Individual participant data (IPD) sharing plan
A managed access procedure will be developed to allow access to other researchers that wish to use the study data for secondary analysis after the closure of the study. These data will not be made openly accessible in line with national, European and international legal, ethical and privacy concerns. Access to the data will be controlled by principal investigator Håkon A. Bolkan and the senior board of PSSC'19. After the study has been completed and the main study paper published, then researchers can apply to principal investigator Håkon A. Bolkan with proposals to access the study data set for future studies. Access to the data set requires approval from the Steering Committee, which comprises representatives from each consortium partner and is chaired by Håkon A. Bolkan. Researchers will additionally need to sign a Data Sharing Agreement to protect the integrity and confidentiality of the requested data. Any shared data will be further minimised and anonymised as much as possible for the requested purpose.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v2.3	01/09/2019	16/10/2019	No	No
Results article	CVD arm results	18/08/2021	17/01/2022	Yes	No
Results article		06/09/2022	07/09/2022	Yes	No
Results article		01/02/2023	17/11/2023	Yes	No
Other publications	Surgical Volume in Sierra Leone: A Comparison Between Population and Facility-Based Data Collection	15/08/2025	18/08/2025	Yes	No