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Fever in Subsaharan Africa

Submission date 02/08/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 14/10/2019	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 15/04/2025	**Condition category** Signs and Symptoms	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Fever is a common symptom that is defined as a higher than normal body temperature. It occurs most often in response to an infection. There are many infections that can cause fever. These infections can be due to many different types of germs (bacteria, viruses, parasites and fungi). ALERRT (The “African coalition for Epidemic Research, Response and Training”) is a group of health institutions that have come together to conduct research that aims to improve care and treatment for people who have an infectious disease in Africa.

Who can participate?
The FISSA study is about adults and children above two months presenting with a febrile illness and without hospitalization in the 14 last days.

What does the study involve?
The FISSA study is an observational study which aims to better understand the main causes of fever, by describing symptoms and signs of your health problem including its severity, the care received and the outcome of this care. The researcher will not influence the patient's care, but simply records what is happening. Medical staff who attend to participants will care for them in the same way as usual. A better understanding of these features will lead to development of new treatments and improve care.

What are the possible benefits and risks of participating?
The care that the participant will receive is exactly the same he/she would receive outside of the study context. It will entail no additional cost to and no blood test or additional examination will be required. The only additional study-specific procedure will be phone calls or on site visits, for which the participant will receive a mobile phone credits/units or a small cash for transportation compensation.

Where is the study run from?
The Study will take place in 16 care centers in sub Saharan Africa (8 in Western, 4 in Central and 4 in Eastern Africa). Recruitment will take place in 11 countries and 8 sites.

When is the study starting and how long is it expected to run for?
The first recruitment is planned for November 25, 2019 and the study is scheduled to last 12 months. Each participant will be followed up for 21 days.

Who is funding the study?
The FISSA Study is funded by European Union through a European and Developing Countries Clinical Trials Partnership (EDCTP) Program.

Who is the main contact?
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Clinical pattern, severity, management and outcome of acute febrile illness in sub-Saharan Africa

Acronym
FISSA

Study objectives
The field of infectious diseases is diverse and fast-moving. Researchers should be prepared to tackle diseases which pose major threats, such as HIV/AIDS, tuberculosis or malaria, but also new emerging diseases before they become major public health threats, such as viral hemorrhagic fevers. African clinical trials network for infectious diseases should be adaptable and have both a generic approach to clinical research and a specific approach depending on the disease. This implies building: (i) networks of clinical centres across as many countries as possible where professionals have been trained in clinical trials and are able to implement standard procedures, (ii) networks of regional and international institutions that bring them in contact with the best specialists in specific fields. To consolidate the setting of this network, to consolidate the setting of this network, the FISSA study is being implemented with the following objectives to document the clinical patterns, severity, management, and outcomes of febrile illnesses in clinical centers across West, Central and East Africa.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/09/2019, Comite National d'Ethique des Sciences de la Vie et de la Sante (CNESVS s /c de l’institut pasteur, 01 BP 490 Abidjan 01, Ivory Coast; +225 41 40 05 55; cnesvscotedivoire@gmail.com), ref: 106-19

Study design
Multi-center prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

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
Febrile illnesses

Interventions
After giving informed consent to participate in the study, each participant will be included and followed for 21 days. Contacts are planned for days 7, 14 and 21 after inclusion. These contacts will be made by telephone or through visits as far as possible. However, unscheduled calls or visits may be made at any time if necessary.

Intervention Type
Other

Primary outcome measure
Clinical status is measured using a three-category ordinal scale (resolved, not resolved, dead) at day 7.

Secondary outcome measures
1. Clinical status is measured using a three-category ordinal scale (resolved, not resolved, dead) at day 14 and day 21.
2. Illness severity:
2.1. In adults:
2.1.1. Ambulatory Simplified Acute Physiologic Score (ASAPS) and modified ASAPS (using ACVPU instead of Glasgow) at days 0, 7, 14 and 21.
2.1.2. Quick Sepsis Related Organ Failure Assessment (qSOFA) at days 0, 7, 14 and 21.
2.2. In children <5 years is measured using the ALgorithm for the MANAgement of Childhood illness (ALMANACH) criteria at days 0, 7, 14 and 21.
3. The proportion of subjects admitted to hospital is measured at day 21.
4. Length of stay in hospital (Initial and/or secondary hospitalization) is measured at day 21.
5. Number of secondary visits is measured at day 21.
6. Number and type of laboratory and radiology tests prescribed/actually performed measured at day 21.
7. Number and type of medications and supportive care prescribed/actually given measured at day 21.
8. Working diagnoses at admission and final diagnoses measured at day 21.
9. Patient satisfaction is measured using a questionnaire at day 21.

Overall study start date
03/04/2018

Completion date
25/11/2020

Eligibility

Key inclusion criteria

1. Ongoing objectively determined fever, as defined by axillary Temperature >37.5°C, or tympanic (or oral or rectal) temperature >38°C.
2. Contactable by the study team at days 7, 14 and 21.
3. Informed consent to participate signed by the patient (adults) or a legally acceptable representative (children or patients with impaired consciousness) with assent from the concerned, where applicable and possible

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
10,000

Total final enrolment
8867

Key exclusion criteria
1. Children under 2 months
2. Hospitalization in the last 14 days

Date of first enrolment
25/11/2019

Date of final enrolment
10/12/2021

Locations

Countries of recruitment
Cameroon

Central African Republic

Côte d'Ivoire

Gambia

Ghana

Guinea

Madagascar

Nigeria

Senegal

Tanzania

Uganda

Study participating centre
Children's Hospital of Diamniadio
Diamniadio
Diamniadio
Senegal
Non applicable

Study participating centre
CHU de Fann/Albert Royer
Dakar
Dakar
Senegal
Non applicable

Study participating centre
Centre de Santé amélioré de Maferinyah
Maferinyah
Maferinyah
Guinea
Non applicable

Study participating centre
CHR d'Ayamé
Ayamé
Ayamé
Côte d'Ivoire
Non applicable

Study participating centre
Urgences du CHU de Treichville
Treichville
Côte d'Ivoire
Non applicable

Study participating centre
St. Francis Xavier Hospital
Assin Foso
Assin Foso
Ghana
Non applicable

Study participating centre
Federal Medical Centre of Owo
Owo
Owo
Nigeria
Non applicable

Study participating centre
Clinical Service Department Fajara
Fajara
Fajara
Gambia
Non applicable

Study participating centre
Les Promoteurs de la Bonne Santé
Yaoundé
Yaoundé
Cameroon
Non applicable

Study participating centre
Obala District Hospital
Obala
Obala
Cameroon
Non applicable

Study participating centre
Hôpital de District de Sibut
Sibut

Sibut
Central African Republic
Non applicable

Study participating centre
Boda District Hospital
Boda
Boda
Central African Republic
Non applicable

Study participating centre
CHU de Befelatanana
Befelatanana
Befelatanana
Madagascar
Non applicable

Study participating centre
HDSS Moramanga
Moramanga
Moramanga
Madagascar
Non applicable

Study participating centre
Korogwe District Hospital
Korogwe
Korogwe
Tanzania
Non applicable

Study participating centre
Uganda Virus Research Institute Clinic
Entebbe
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Sponsor information

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EDCTP

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Sponsor type
Research organisation

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ROR
https://ror.org/031jv9v19

Funder(s)

Funder type
Research organisation

Funder Name
European and Developing Countries Clinical Trials Partnership

Alternative Name(s)
Le partenariat Europe-Pays en développement pour les essais cliniques, A Parceria entre a Europa e os Países em Desenvolvimento para a Realização de Ensaios Clínicos, The European & Developing Countries Clinical Trials Partnership, European and Developing Countries Clinical Trials, EDCTP

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Once the results are considered final, arrangements will be made for the communication of the results to the community, in the most appropriate way, with the active participation of the health authorities. We are intending to ublish the description of Clinical patterns, severity, management and outcomes of febrile illnesses in sub-Saharan Africa by mid 2021.

Intention to publish date
31/05/2025

Individual participant data (IPD) sharing plan
Researchers can request ALERRT for access to the anonymized data for well-defined research or secondary analyses via a controlled access procedure. A Data Access Committee (DAC) will be set up. This Committee will review the request and provide timely an answer to the Requestor. In case of positive evaluations data will be shared by a data sharing agreement between the Platform Host and Requestor. Data will be shared from the Platform Host to Requestor by means of secure encrypted data transfer.

IPD sharing plan summary
Available on request