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Use of aspiration as an intervention for filarial hydrocele

Submission date
07/03/2022

Recruitment status
No longer recruiting

Registration date
08/03/2022

Overall study status
Completed

Last Edited
08/03/2022

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Lymphatic filariasis (LF) is a parasitic disease caused by microscopic, thread-like worms. It is ranked by the World Health Organization (WHO) as the second leading cause of disability in the world. A significant proportion of the public health problem represented by LF is due to illness and disability not only related to lymphedema (a build-up of fluid in soft body tissues) but also to hydrocele (a build-up of fluid in a sac in the scrotum). It is estimated that 40 million people are living with chronic forms of disease, of whom estimated 25 million men are affected by hydrocele. Disease manifestations such as urogenital disorders are known to be the cause of social stigma, physical deformation, loss of self-confidence, problems with sexual activities, lower chances for employment and loss of work due to frequent attacks of fever, pain and adenolymphangitis. For advanced stages of hydroceles, the only option is hydrocelectomy (surgery to remove or repair a hydrocele). However, due to the lack of capacity in in-country health centres and cost restrictions, this is an uncommon practice in rural areas.
A small study showed that ultrasound-guided aspiration (removal of fluid) resulted in long-term improvement of hydrocele in patients with the stages 2 and 3. However, in that particular study, a control group without intervention was missing.
This study aims to compare patients who will receive ultrasound-guided aspiration as intervention to those who will be observed without intervention. The control group will receive ultrasound-guided aspiration at the end of the study in case this method proves to be effective. Showing the effectiveness of hydrocele aspiration in this pilot study will be followed by the next step, which will be a confirmatory study with the aim of establishing the procedure as standard treatment for LF-infected patients presenting with early hydrocele stages.

Who can participate?
Healthy men aged 18 – 55 years with simple hydrocele determined by ultrasound. Hydrocele ultrasound stages 2- 4 will be included, however, participants with stage 4 should not have fluid volume more than 500 ml as determined by ultrasound.

What does the study involve?
Participants are randomly allocated to the intervention group or the control group. Ultrasound-guided aspiration of hydrocele fluid at study onset will be conducted for the intervention group, while the control group will receive no intervention. The participants will be followed for 2 days

for adverse events, after which visits will be conducted at 6, 12 and 18 months after the intervention. During the visits, ultrasound will be conducted for both the intervention and control groups.

What are the possible risks and benefits of participating?
The benefits of participation may include one or more of the following: improvement of hydrocele size and/or stage, improvement in general health, and free medical treatment for common illnesses (e.g. cold, malaria, diarrhoea, wound dressing after cuts) during the treatment period and at follow-up time points. Risks to the participants are associated with the possible bruising due to the blood sampling and risk of bleeding or infection due to the aspiration procedures. Due to the use of local anesthesia, a local numbness can occur.

Where is the study run from?
1. Kumasi Centre for Collaborative Research (KCCR) (Ghana)
2. Kwame Nkrumah University of Science and Technology (Ghana)

When is the study starting and how long is it expected to run for:
January 2021 to March 2024

Who is funding the study:
Research Networks for Health Innovations in Sub-Saharan Africa sponsored by the Federal Ministry of Education and Research (BMBF) (Germany)

Who is the main contact?
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Protocol serial number
TAKeOFF-6-0618-GH

Study information

Scientific Title
Efficacy of ultrasound-guided hydrocele aspiration to prevent surgical intervention

Acronym
TAKeOFF – HYD-Asp

Study objectives

A significant proportion of the public health problem represented by lymphatic filariasis (LF) is due to morbidity and disability not only related to lymphedema (LE) but also to hydrocele. For advanced stages of hydroceles, the only option is hydrocelectomy. The objective of this study is to evaluate the efficacy of ultrasound-guided aspiration for long-term improvement of hydrocele size and as to whether it can stop hydrocele progression to a size obligatory of surgical intervention (hydrocelectomy).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/01/2022, Committee on Human Research, Publication and Ethics, Kumasi Ghana (School of Medicine and Dentistry, KNUST, University Post Office, Kumasi, Ghana (+233 (0) 3220 63248, +233 (0)20 5453785; chrpe.knust.kath@gmail.com, chrpe@knust.edu.gh), ref: CHRPE/AP /029/22

Primary study design
Interventional

Study design
Randomized controlled interventional pilot study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hydrocele due to lymphatic filariasis

Interventions
After screening, volunteers who meet the inclusion criteria will be randomly assigned to one of the two study arms. Randomization to the study arms will be conducted by central randomization. The participants for the study will be recruited and assigned a study identification number (ID). The study ID and hydrocele stage information of the eligible participants will then be sent to the data management team in Bonn who will assign the IDs to a randomization code. Participants with hydrocele stage 2 will be separately randomized from participants with hydrocele stages 3 or 4 in order to obtain equally distributed numbers of the different stages in each study arm. In case of patients with bilateral hydrocele, the side with the higher volume will always be taken into account for randomization arm allocation. The codes will be retrieved from a computer-generated randomization list. After randomization in Bonn, the team in Ghana will be informed in writing about the study arm assignment of each individual participant. This procedure assures that the assignment of the participants to the respective intervention arms will not be biased by any personal involvement. After randomization, the intervention can be initiated according to the randomization code.

Participants will be randomly assigned into one of the two study groups:
Intervention group (Group A) n = 30: ultrasound-guided aspiration of hydrocele fluid at study onset.
Control group (Group B) n = 30: no intervention at study onset; if this method proves to be effective, ultrasound-guided aspiration will be offered at the end of the study.

For each participant in the intervention group (A), the ultrasound-guided aspiration procedure will be performed once and will last no more than 45 minutes. The duration of follow-up is 18 months

Intervention Type
Procedure/Surgery

Primary outcome(s)
Improvement of hydrocele stage, assessed using ultrasound and defined as a reduction in at least one hydrocele stage, between pre-aspiration and 12 months after aspiration

Key secondary outcome(s)
1. Improvement of hydrocele stage, defined as a reduction in at least one hydrocele stage at 6, 12, or 18 months after aspiration. Hydrocele stage is measured using ultrasound, as defined by Debrah et al., 2007
2. Improvement of hydrocele size by comparing the testis to scrotum ratio at 6, 12 and 18 months post-aspiration. An increase in the ratio will be defined as an improvement (quantitatively calculated as described by Turgut et al., 2007)
3. Improvement of hydrocele stage (staging according to the recommended WHO guidelines) at 6, 12 or 18 months post-aspiration. Improvement is defined as a reduction of at least one hydrocele stage
4. Change of the grade of penis burial between pre-aspiration and 6, 12 and 18 months post-aspiration, defined on a scale of 0-4, with 0 being no burial and 4 being complete burial (grading according to WHO surgical approached to LF hydrocele)
5. Curative effect, defined as no fluid accumulation (no relapse) determined using ultrasound after aspiration, measured at 6, 12 and 18 months after aspiration

Completion date
30/03/2024

Eligibility

Key inclusion criteria
1. Ultrasound determined hydrocele stage 2 – 4 as described by Debrah et al., 2007, however, participants with stage 4 should not have fluid volume more than 500 ml as determined by ultrasound
2. Male patients aged 18 - 55 years
3. Resident in the endemic area for 2 years or more
4. Able and willing to give informed consent to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Male

Key exclusion criteria
1. Age <18 or >55 years
2. No hydrocele or stage 1 hydrocele(s) only
3. Hydrocele of unknown cause
4. Stage 4 hydrocele with a fluid volume >500 ml determined by ultrasound and other stages that require hydrocelectomy
5. Thickened, fibrosed or calcified tunica vaginalis assessed by ultrasound
6. Haemorrhagic fluid or necrotic testis(es) assessed by ultrasound
7. Resident in the area for <2 years
8. Hernia assessed by ultrasound
9. History of bleeding tendencies
10. History of haemophilia
11. Chronic liver disease
12. Coagulopathies
13. History of severe allergic reaction or anaphylaxis due to anaesthetic drugs
14. Participation in drug trials concurrent with this study
15. Any other condition or severe comorbidities (except for features of the filarial disease) that, in the opinion of the study clinician, would risk the safety or rights of a participant or would render the subject unable to comply with the protocol.
16. Intake of blood thinners (warfarin, heparin, aspirin)
17. Intake of diuretics
18. Unable to give informed consent

Date of first enrolment
07/03/2022

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
Ghana

Study participating centre
Kumasi Centre for Collaborative Research (KCCR)
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Kumasi
Ghana
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Sponsor information

Organisation
Kumasi Centre for Collaborative Research (KCCR)

Funder(s)

Funder type
Research organisation

Funder Name
Research Networks for Health Innovations in Sub-Saharan Africa sponsored by the Federal Ministry of Education and Research (BMBF), Germany

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Not expected to be made available