pGO-Tibia

A Masked, Randomized Controlled Trial to Evaluate Local Gentamicin versus Saline in Open Tibia Fractures

pGO-Tibia: a masked, randomized controlled trial evaluating Gentamicin versus saline in Open Tibia fractures

ClinicalTrials.gov Identifier: NCT03559400

INFORMED CONSENT FORM

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Participant Information Consent Form

Title of Research: A Pilot Masked, Randomized Controlled Trial Evaluating Locally-Applied Gentamicin versus Saline in Open Tibia Fractures

Name and affiliation of researchers: This study is being conducted by Dr. Billy Haonga and colleagues of the Muhimbili Orthopaedic Institute in Dar es Salaam with the support of Dr. Saam Morshed and Dr. David Shearer from the University of California, San Francisco, **with funding from the Orthopaedic Trauma Association, Orthopaedic Research and Education Foundation, and National Institutes of Health.**

You are being asked to take part in this study because you have a fracture of your tibia. You will be asked to provide consent should you choose to participate in this study.

Background: A tibia fracture is a break of the shin bone in the lower leg. In more severe cases, the break can cause an opening in the skin, which is called an open fracture. Open fractures have a high risk of infection and poor bone healing. The current standard of care is to do a surgical cleaning of the fracture, called debridement, followed by stabilization of the fracture using a cast or metal implants. Despite these efforts, rates of infection from open fracture remain as high as 40%. Prior studies have shown that injection of antibiotics at the site of the open fracture may decrease the risk of infection, but these studies have not been conclusive.

Purpose of research: The purpose of this study is to determine if injection of the antibiotic gentamicin at the site of open tibia fracture reduces the rate of infection when compared to injection of saline without antibiotics in adults.

Procedure of the research, what shall be required of each participant and approximate total number of participants that would be involved in the research: If you decide to participate in this study and sign the consent form you will be enrolled in the study. Once enrolled, you will be randomly assigned to receive surgery with one of two treatment options: the control treatment (surgical debridement with the addition of saline injection, without antibiotics), or the active treatment (standard of care with the addition of local antibiotic injection). Random assignment means the researchers will use a computer program to determine which treatment you receive. There will be a 50/50 chance of receiving either treatment (local antibiotics or saline without antibiotics). You will then undergo surgery to debride your tibia fracture. The surgery will be performed in the same manner regardless of which treatment you are assigned, with the only difference being the placement of antibiotic or saline into the wound at the end of the surgery. The surgeon will clean the fracture and stabilize using a cast or metal implants at their discretion, which will not be altered by participation in the study. After surgery you will not know whether you received the local antibiotic or saline. Only the research personnel preparing the solution, not the surgeon, will know which treatment you were randomly assigned to receive. This is done to prevent any bias in how you are treated based on the treatment group.

You will return for standard postoperative follow up appointments with your surgeon whether or not you participate in the study. These appointments will occur at 2 weeks, 6 weeks, 3 months, 6 months, 9 months, and 12 months after surgery. At these appointments, you will be examined by a doctor, x-rays will be obtained to monitor healing, and your activity will be advanced. You may be asked to complete a short questionnaire and/or a short interview about how you are doing after surgery. These may include questions about your quality of life and your ability to work.

This study will take place in the Orthopaedic and Traumatology Directorate at Muhimbili Orthopaedic Institute in Dar es Salaam, Tanzania.

Experimental treatment: The experimental treatment that you may be randomized to receive, is a solution of Gentamicin antibiotic dissolved in water (80mg of liquid
Gentamicin diluted in 40mL normal saline) at the site of your wound. Local Gentamicin has been previously approved by the Tanzania Food & Drug Authority (TFDA) (Please contact TFDA for registration number).

Control treatment: The control treatment that you may be randomized to receive is a solution of water (40mL normal saline) at the site of your wound.

Risks: You will be assigned to a treatment program by chance, and the treatment you receive may prove to be less effective or to have more side effects than the other study treatment. Specifically, if you are assigned to receive local gentamicin, it is possible that it may negatively affect local wound or bone healing.

Benefits: While previous studies have suggested that gentamicin reduces the rate of infection, you may not receive the drug, or the drug may prove to be less effective than anticipated. The information gathered in this study may benefit society by helping to understand the effects of locally injected antibiotics for open fractures.

Confidentiality: All information collected in this study will be given code numbers. Reported data will not be linked to you in any way. No name or identifier will be used in any publication or reports from this study. However, as part of our responsibility to conduct this research properly, we may allow regulatory authorities, sponsors, or officials from the National Health Research Ethics Committee to have access to your records.

Voluntariness: Taking part in this study should be out of your own free will. You are not under obligation to participate. Research is entirely voluntary.

Alternatives to participation: If you choose to not participate in the study, you will receive the current standard of care treatment (surgical debridement with no local antibiotics) for your tibia fracture. You will not be randomized and will not receive the experimental treatment (surgical debridement with local antibiotics). Choosing to not participate in the study will not otherwise impact your treatment in this hospital/institution in any way.

Withdrawal from the research: You may choose to withdraw from the research at any time without having to explain yourself. You may also choose not to answer any question you find uncomfortable or private.

Consequence of Withdrawal: There will be no consequence, loss of benefit or care to you if you choose to withdraw from the study. Please tell the study doctor

if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation.

Costs/Compensation: You will be expected to pay the standard fees for treatment that you would incur regardless of participation in this study. You will be provided with the local antibiotic free of charge. Your follow-up radiographs and consultant fees will be provided at no cost to compensate for the added time to complete study-related follow up questionnaires. You will receive cash incentives to cover the costs associated with study-related hospital visits to help cover expenses such travel costs and missed work.

Treatment and Compensation for Injury: In the event of any trial-related injury, MOI will provide medical treatment to you. Depending on the nature of the treatment, costs of treatment will be billed to you or your insurance, covered by MOI, or covered by the study. Participants will not be directly compensated for complications as a result of participation. For more information, please contact the National Institute for Medical Research (NIMR) at +255-22-2121400 or Dr. Billy Haonga (Principal Investigator) at +255 22 215 2937.

Contacts: If you have any question concerning this study, please do not hesitate to contact Dr. Billy Haonga (Principal Investigator) at +255 22 215 2937.

Other Investigators: Dr. Edmund Eliezer (MOI), Dr. David Shearer (UCSF), Dr. Saam Morshed (UCSF)

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

Further, if you have any concern about the conduct of this study, your welfare or your rights as a research participant, you may contact:

The National Institute for Medical Research (NIMR)
3 Barack Obama Drive
P. O. Box 9653
11101 Dar es Salaam, Tanzania
Tel: +255-22-2121400
Email: hq@nimr.or.tz

Statement of person obtaining informed consent:

I have fully explained this research to _____ (patient). I have given sufficient information about the study, including that on procedures, risks and benefits, to enable the prospective participant to make an informed decision to or not to participate.

NAME: _____

DATE: _____ SIGNATURE: _____

Statement of legally authorized representative giving consent:

I have read the information on this study/research or have had it translated into a language I understand. I have also talked it over with the interviewer to my satisfaction.

I understand that participation is voluntary for the person I am representing.

I know enough about the purpose, methods, risks and benefits of the research study to decide that I want this person to take part in it.

I understand that the patient may freely stop being part of this study at any time without having to explain myself.

NAME: _____

DATE: _____ SIGNATURE: _____

If participant is illiterate, please provide Witness signature:

WITNESS NAME: _____

DATE: _____ SIGNATURE: _____