

Addendum A - Informed consent

Research study: Epithelial debridement - Is it an effective intervention to decrease pain in patients suffering from bullous keratopathy?

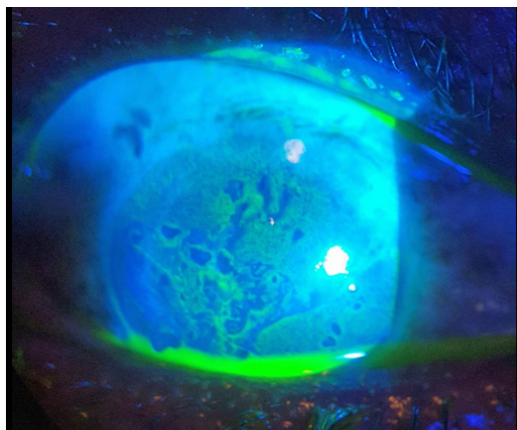
Investigating doctor: Dr Daemon McClunan MBChB, DipOphth (SA)

Why is this study being done?

- We would like to study whether a procedure called “Epithelial debridement”, which is helpful in another eye condition similar to yours, will work for your condition as well
- We want to test whether the procedure will decrease the pain you are experiencing
- We need to make sure the procedure is safe

Why are you being asked to take part?

- You have an eye condition called “Bullous keratopathy”. This is when blisters form on the front of the eye because of swelling in this area. These blisters cause the pain and scratchiness which you are feeling



How many people will take part in the study?

- We aim to have at least 20 people take part

How long will the study last?

- The study will be done over a period of one year from 1 April 2016 to 31 March 2017.
- You will be followed up for six months after the procedure has been done.

What do we do to decide if you are eligible to be take part?

- Doctor will make sure that you do have the condition known as Bullous keratopathy
- Doctor will make sure you don't have signs of other eye conditions which could put you at higher risk of having problems from the procedure
- Doctor will discuss the study with you and make sure you are happy to take part

Do I have to take part in the study?

- No. It is completely up to you whether you would like to take part in the study
- If you decide not to take part you will be treated as usual
- You can decide to pull out of the study at any point

What will happen if you decide to take part in the study?

- After discussing any questions you have with the doctor you will need to sign this form to show that you have agreed to take part
- The procedure will be done on the earliest day that suits you and where doctor is available
- Doctor will record some information regarding your condition and also take photos of your eye
- After this the procedure will be done in the minor procedures room at the eye clinic
- You will need to return to the Groote Schuur eye clinic for check-ups at one week, one month, two months, three months and six months after the procedure. Doctor will again record some information and take photos of your eye during these check ups

What does the procedure involve?

- The doctor will put drops in your eye for 5 minutes which will kill any germs in your eye and numb the eye so you won't feel pain during the procedure.
- You will need to lie down on a bed and keep still for about five minutes while the doctor is working on your eye through a microscope
- Doctor will use an instrument to keep your eyelids open for you and then will rinse the eye clean.
- The blisters will then be scraped off the eye using a blunt spoon and a small sponge
- The eye will be rinsed again
- A soft contact lens will be placed on your eye to protect it while it is healing
- You will be given a follow up date

- Doctor will explain that you should come to the Groote Schuur emergency area urgently if you experience any Redness, Sensitivity to the light, decreasing Vision or worsening Pain (RSVP)
- You will go to the pharmacy to collect some pain tablets and drops which you will need to put in the eye four times a day
- You can expect the eye to become painful about thirty minutes after the procedure and this could last for around one week
- It is important that you use the drops as prescribed and keep the eye clean for the first week after the procedure. This means no swimming. You can still bath or shower but you should avoid getting water into the eye. Don't rub the eye or put your fingers into your eye. If the contact lens falls out, don't put it back in. Keep it in a container or piece of clean tissue paper and contact the doctor.

What are the benefits to you for being in the study?

- We expect the procedure to make the pain in your eye less for a period of three to six months. Note that we do not expect the pain to go away completely but only to become less painful.
- There is a chance that the procedure could improve your vision for a while as well
- You will be helping us to understand your condition better which may help other patients in future

What are the risks of this study?

- The biggest risk is that you could get an eye infection called "Infective keratitis" after the procedure. We will do everything possible to prevent this, but if you do get this infection you will need to be admitted to the hospital for treatment. Treatment usually means drops onto the eye every hour. If the drops don't work you might need to go for an operation.
- The other risk is that we expect that the procedure will make your pain worse for the first week after the procedure while the eye is healing
- There is also a chance that the procedure might not actually decrease your pain. Because this is an experimental procedure we cannot be sure that it is going to work.

What if something goes wrong?

- The University of Cape Town (UCT) has insurance cover for the event that research-related injury or harm results from you taking part in the trial. The insurance will pay all reasonable medical expenses
- The University will not be liable for any loss, injuries and/or harm that you may sustain where the loss is caused by

- The use of unauthorised medicine or substances during the study
- Any injury that results from you not following the protocol requirements or the instructions that the study doctor may give you
- Any injury that arises from inadequate action or lack of action to deal adequately with a side effect or reaction to the study medication
- An injury that results from negligence on your part

What other choices do you have?

- There are drops which you can use which might help make your pain less, but often they don't help when the condition has become quite bad.
- There are other surgery procedures which can be done but we don't use them here at Groote Schuur because they haven't been shown to work as well as we would like.
- The best treatment for this condition is to replace the area of the eye that is affected with the same part from another person who has died. This is called a "Corneal transplant". If you want to have it done at Groote Schuur you will be put on a waiting list. If you want to have it done sooner you can have it done at a private eye specialist for around R50 000.

What will happen when the study is over?

- You and the doctor will discuss how your condition is doing and decide on what treatment will be best for you afterwards.
- We will let you know what the results of the study were if you would like to know

Who will see the information which is collected about you during the study?

- Your name and contact details will not be collected
- Only the doctors involved in the study will see the information collected but the results of the study will be made available to the public

Who do I contact if I have any questions about the study?

- Contact Dr McClunan via cell: 0846047600 or E-mail dae.mcc@gmail.com if you have any questions. If you have an emergency please go to the Groote Schuur emergency area to be seen by the casualty doctor who can then contact Dr McClunan after you have been examined

X

Doctor

X

Patient full name and signature

X

Witness (If patient illiterate)