Practical information for participating Pharmacists about the project:

# Low dose of oral steroids in the treatment of painful acute otitis externa (swimmer's ear)

## A. Summary, significance and innovation

Otitis externa is a frequent problem worldwide, especially in the tropics. The pain and swelling often makes proper topical treatment difficult. Although scientifically unproven, some GPs use oral steroids. This procedure is not officially recognised. Consequently, this is an off label prescription and may pose some legal risk.

This study aims to investigate if oral steroids shorten the course of symptoms. Furthermore to investigate if oral steroids increase side effects. The study design is a randomized controlled clinical trial. If the clinical observation made by doctors already using oral steroids can be proven to be correct then it might reduce pain and complications in a far greater number of patients. If oral steroids have no beneficial effect, or even harmful effect, then it is important that this information is made public so GPs currently using oral steroids can change. Thus, any of the possible outcomes of this study has the potential of altering current practice.

## B. Study outline / logistics

Patients attending their GP who are diagnosed as having an otitis externa are noted with age and gender on a "GP screening sheet". They are asked if they accept being evaluated for participation in a study. A suggested introduction would be "*There is a study going on at James Cook University concerning a new treatment of this type of ear inflammation. Your case may be suitable. May I ask a few questions to see if you fit the inclusion criteria? If you do you will be given more information before deciding to participate.*" If they say no nothing more needs to be done.

**If they say yes the GP follow the instructions on the inclusion sheet. Then tick the appropriate boxes and note the unique ID number of the "inclusion sheet" on the GP screening sheet.** If they do not fulfil the inclusion criteria the GP retain the inclusion sheet.

## C. Pharmacists are expected to:

If patients fulfil the inclusion criteria the GP give the inclusion sheet and any written prescription to the patient and also advise the patient to go to any pharmacy on a list with specified pharmacists participating in this study. You as a pharmacist are expected to:

1. Check that all boxes in item 2 on the "inclusion sheet" are ticked by the GP (a requirement to be eligible for the study). If they are not then the patient is not eligible.
2. Check that patient has marked current level of pain (item 1 on the back side of the "inclusion sheet"). If not ask them to do that.
3. Check that the patient was not prescribed oral corticosteroids by the GP.
4. If 1+2+3 above are OK then the patient is eligible for the study. Give the patient further written "patient information". Let the patient read it (you may prepare the prescriptions given by the GP while the patient reads the information). Ask if they have any questions. If

you are uncertain about the answer ring any of the phone numbers at the end to get clarification. Once the patient is satisfied ask if they are willing to participate.

5. If patients reject participation retain the "inclusion sheet". Do nothing more concerning this study. However, if the patient accepts participation give them the "consent form" to be signed by the patient and by you. After it is signed by the patient and you retain the patient "consent form".
6. For patients accepting participation:
   a) Ask them to provide contact details (item 2 on the back side of the "inclusion sheet").
   b) Give them a sequentially numbered "can of study tablets" being either oral corticosteroids or placebo. Retain the "inclusion sheet" the patient has and write on it the id-number of the can that was given to the patient.
   c) Take one prepared patient envelope. Open it and write the unique ID number from the "inclusion sheet" on the patient diary and the satisfaction questionnaire. Put them back into the envelope. Store the "inclusion sheet" until picked up by the research co-ordinator.
   c) Give the patient the envelope containing; patient information, a daily diary and a satisfaction questionnaire later to be sent directly to the study co-ordinator by mail.
   d) Give the patient the prescriptions from the GP (not being part of this study).

The extra time needed by the pharmacist is estimated to be 10 minutes on each patient. We expect each clinic to include in total 250 patients in Cairns with surroundings during the wet season 2014-2015.

## D. Exclusion criteria

Patients experiencing worsening of pain ≥24 hours after initiation of treatment are to be excluded. The patient information will tell those patients that they must immediately stop taking the "study tablets" and immediately seek medical advice.

## E. Ethical requirements

The study will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964 and later revisions. It is the responsibility of the chief investigator to obtain approval of the Study Protocol from appropriate ethics committee and to keep the ethics committee informed of any Serious Adverse Events and amendments of the protocol.

## F. When?

The preliminary timeline is that data collection should take place from November 2014 until 250 patients are included.

## G. Remuneration

We currently have no budget for remuneration to the pharmacy.

## H. Questions?

This project is done in collaboration with North Queensland Practice Based Research Network (contact person Margaret Spillman). In case you want more information please contact any of the investigators. They are happy to send you more written information or to answer any questions you may have:

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