Practical information to participating GPs 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 acute 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 do say no nothing more needs to be done.

If they say yes 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 retain the inclusion sheet. If they fulfil the inclusion criteria give the inclusion sheet and any written prescription you may have given to the patient and also give the patient the list with specified pharmacists. These pharmacists will give the patient further written information, ask for participation and give patients accepting a written consent form to sign.

The pharmacist will give the patient a "study tablet" being either oral corticosteroids or placebo. The patients will be asked to complete a daily diary and a questionnaire later to be sent directly to us by mail. This will be our only source of information.

You must not prescribe oral steroids to these patients. Furthermore, in the written information patients will be advised that if the symptoms get worse they should go back to you, or if you are unavailable attend another GP or the emergency department of the nearest hospital. Otherwise we will not interfere with your management or follow up of the patient.

The extra time needed by the GP is estimated to be less than 3 minutes on each patient. We expect each clinic to include between 8-15 patients during the wet season 2014-2015.

C. 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 as soon as possible seek medical advice.

D. 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.

E. When?

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

F. Remuneration

We currently have no budget for remuneration to the clinic or the participating GP. We will seek finance to this but the outcome is uncertain.

G. 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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