

New Zealand General Practice Dermoscopy Study Participant Information Sheet^C

You are invited to take part in a General Practice study on new methods of skin cancer detection.

Background to the study

New Zealand has one of the highest rates of skin cancers in the World. Skin lesions can be difficult to assess as benign lesions can be indistinguishable from skin cancers. Dermoscopy (examination of the skin with a hand held microscope) shows underlying skin structures not able to be seen with the naked eye. Diagnostic accuracy is enhanced using this method in trained hands, ie skin cancer specialists. It is not clear if dermoscopy is useful in the General Practice setting. A short training session (3-4 hours) has been designed to teach GP's basic dermatological features. Just 3 features are used during skin examination making it the simplest method to date.

This study will help to determine if this training and method of skin assessment will allow GP's to detect more skin cancers than the current "naked eye" assessment. It will also help to determine if benign (non cancerous lesions) can be distinguished from skin cancers. Ethical approval has been granted to carry out this study.

Your Participation

Your participation in this study is entirely voluntary (your choice). If this study confirms this new method of skin assessment detects more skin cancers it may have a huge impact on how doctors assess skin lesions in the future.

Approximately 200 GP's around New Zealand are involved in this study. Their regular patients are being invited to take part in the study. Your involvement will not require any additional visits other than those you and your doctor would have required if you were not participating in the study.

Your GP has been assigned to the group to **continue with standard methods of assessment**. This is a crucial part of the study as it allows scientific comparison for those GP's using the new method.

Your care will not be compromised in anyway as you will be receiving care based on current best practice.

Using current best practice there is a possibility that you will have a lesion assessed as needing a biopsy or excision, but the lab analysis shows it to be benign. There is also a possibility that a lesion will be assessed as benign when it is in fact a skin cancer. Review of any skin lesion that irritates or changes is essential. Regular reviews will detect skin cancers over time.

Your doctor will be supplying us with some basic information about your age, sex and NHI number, size and site and clinical diagnosis of the lesion(s). If you require any treatment or investigation your doctor will supply us with a copy of those results. No material that could personally identify you will be used any reports of the study.

Results of the Study

Your GP will be given the results of the study and it is our intention to publish the results in an international medical journal. This will allow the results to be scrutinised by the international medical community.

If you would like to be contacted with a summary of the results please let us know by writing to us or emailing and we can arrange this for you. There will be a delay of about 6 months from the end of the study until results will be available.

Your Rights

If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact a Health and Disability Advocate, telephone

- Northland to Franklin 0800 555 050
- Mid and Lower North Island 0800 42 36 38 (4 ADNET)
- South Island except Christchurch 0800 377 766
- Christchurch 03 377 7501

Your participation in this study will be of tremendous benefit in helping us find better ways to diagnose skin cancer. Should you have any concerns or complaints arising from your participation in this research, or if you would simply like more information about the study, you may contact me –

Dr Mark Foley P.O.Box 382 Blenheim Tel 03 578 1665 Email: dermoscopystudy@elanzclinic.co.nz
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Thank you very much for considering taking part in this study.