Ex-vivo confocal microscopy: diagnostic accuracy, acceptability & feasibility for skin cancers and inflammatory dermatoses

ACTRN12623000629639

Status	RECRUITING
Sponsor	Royal Prince Alfred Hospital
Enrollment	196 participants

Plain Language Summary

When a suspicious skin lesion is removed for analysis, it is currently processed through traditional laboratory methods — sliced, stained, and examined under a microscope by a pathologist. A new technology called ex-vivo confocal microscopy (fevCM) allows skin tissue to be scanned with a very high-powered laser microscope very quickly, producing detailed images without the time-consuming staining process. This could potentially speed up diagnosis and help surgeons know during the procedure whether a cancer has been fully removed.

This study will compare the accuracy of this new microscope approach against the standard pathology method for diagnosing skin cancers (such as basal cell carcinoma, squamous cell carcinoma, and melanoma-related lesions) and inflammatory skin conditions.

You may be eligible if you are 18 or older and have one or more skin lesions that your doctor recommends having biopsied or removed as part of your standard care. No extra skin samples beyond what your doctor already recommends will be taken. People who are unwilling to provide consent or are considered unsuitable by their treating clinician would not be eligible.

Key Eligibility Criteria

Inclusion (4)

- Aged 18 years or older
- Have a clinician-identified lesion that is consistent with basal cell carcinoma (BCC), squamous cell carcinoma (SCC), inflammatory dermatosis (including but not limited to dermatitis, psoriasis, rosacea, lichen planus, cutaneous lupus, etc.), or biopsy-proven lentigo maligna (LM) with a residual pigmented macule.
- Have a lesion needing biopsy or excision as per clinical evaluation, that is to be collected by punch biopsy, elliptical excision, excision with margin control or shave excision depending on the lesion itself
- Be willing and capable to provide informed consent and be willing to participate and comply with the study requirements.

Exclusion (2)

- Be unwilling or unable to provide informed consent or participate in the study
- Be deemed unsuitable by the treating clinician

Locations (1 total)

Royal Prince Alfred Hospital - Camperdown, NSW, Australia