

STATISTICAL ANALYSIS PLAN

Official Title: *Utilization of a Cutaneous Therapy In Situ Microdevice*

NCT Number: *NCT Not Yet Assigned*

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Sponsor: University of California, San Francisco

Overview

This is a feasibility study. The primary goal is to determine whether high-quality tissue suitable for multi-parameter analysis can be obtained following microdevice placement and retrieval. The focus is on qualitative assessment, not formal hypothesis testing.

Primary Analysis Plan

A small region of tissue surrounding the microdevice will be analyzed by immunohistochemistry (IHC), immunofluorescence (IF), and/or spatial transcriptomics to evaluate local anti-inflammatory effects of microdosed agents. The main purpose of this study is qualitative feasibility-- to assess whether IHC, IF, and/or transcriptomic approaches are technically achievable and interpretable from retrieved tissue.

Outcome Summary

Results will be summarized descriptively, including:

- Ability to obtain usable tissue
- Whether IHC/IF/spatial data are technically interpretable

No formal sample size justification or powered hypothesis testing is planned.