UCI Institutional Review Board
Closing Report

Application #: 2468
Lead Researcher Name: NELSON,JOHN
HS#: 2012-9092
Title: Combined Bipolar Radiofrequency (RF) and Pulsed Dye Laser (PDL) Treatment of Port Wine Stain Birthmarks

1. **Status of Study at Closure**
   a. ○ No subjects were accrued.
   b. ◉ - Subject accrual (i.e., recruitment and enrollment) is complete.
   - All subject specimens, records, data have been obtained (i.e., no further collection of data/information from or about living individuals is required).
   - No further contact with subjects is necessary (i.e., all interactions or interventions are complete and no further contact with enrolled subjects is necessary).
   - Analysis of subject identifiable data, records, and specimens are complete (i.e., use or access to subject identifiable data and review of source documents by study sponsors is no longer necessary).

- **Subjects**
  a. Total number of subjects approved by the IRB: 30
  b. Indicate the number of subjects accrued since the **last** IRB new/continuing review: 7
  c. Indicate the **total** number of subjects (including the number in b, above) accrued since the **initial approval** of the study: 22
  d.**The total number of subjects accrued exceeds the total number of subjects approved, please provide the reason(s) here:**

  e. Indicate the total number of subjects accrued since the **initial approval** of the study, **by ethnic origin**:
  (NOTE: a subject can be counted in more than one category if the subject identifies him/herself as a member of more than one ethnic group.)

  Total # American Indian/Alaska Native: 0
  Total # Asian/Pacific Islander: 4
  Total # Black, not of Hispanic origin: 0
  Total # Hispanic: 5
  Total # White, not of Hispanic Origin: 13
  Total # Other/Unknown: 0

  f. Indicate the total number of subjects accrued since the **initial approval** of the study, by gender:

  Male #: 14 **Female #:** 8

  g. **The University of California complies with the federal regulations for the protection of human subjects that require equitable subject selection, and with the National Institutes of Health policy regarding gender and ethnic representation in human research populations. If the gender and ethnic composition of subjects accrued for this study is not equitably representative of the pool of potential subjects in Orange County, please provide an explanation here.**

- **Subject Withdrawal(s)**
  a. **Involuntary Withdrawal(s):** Did the researchers withdraw any subject(s) from this study because of medical problems or other complications?
  ○ YES ◉ NO

  If yes, please state how many and provide the reason(s) here:

b. **Voluntary Withdrawal(s):** Did any subject voluntarily withdraw from the study?
(•) YES ( ) NO

If yes, please state how many and provide the reason(s) here:

Two subjects did not finish all of the proposed follow-up visits due to conflict of their life style.

- **Adverse Events**

a. **Adverse Events Reported to the IRB**
N/A

b. **Adverse Events not Reported to the IRB:**
Were there any adverse events that were not reported to the IRB?
( ) YES (•) NO

If yes, indicate why an adverse event report(s) was/were not submitted:

c. **Data Safety Monitoring Board (DSMB) Data:**
Was there a DSMB for this study? ( ) YES (•) NO

If yes, please describe briefly the DSMB assessment data:

Uploaded Documents:

- **Protocol Deviations**

List any protocol deviations that were not reviewed and approved by the IRB and indicate why a protocol modification request was not submitted.

none

Note: All protocol modifications and planned deviations (including those approved by the sponsor) must have prior approval from the IRB except to avoid an immediate apparent hazard to the subject.

- **Study Results**

a. Summary:
Provide a brief summary of any results (preliminary or final) obtained in the study. If the study is part of a cooperative group or multicenter trial, this should be indicated and a copy of the most recent group-wide progress report attached.

A total of n = 22 subjects were enrolled in the study. Two subjects did not finish all of the proposed follow-up visits. Mild adverse effects such as erythema, edema, and purpura were observed and resolved spontaneously within four weeks. There appeared to be no differences in the mild responses evaluated between the two treatment modalities and recovery of edema and purpura observed by the 4 week visit. Scabbing was seen on PDL test sites on 7 subjects; on RF+PDL test sites on 7 subjects at the 1 week follow-up visit. There is no any clear association of scabbing with PDL alone as compared to RF+PDL. Scabbing resolved spontaneously in all subjects within four weeks. Hypo-pigmentation was observed on one RF+PDL test site at the 4 weeks follow-up on one subject. The hypo-pigmentation resolved spontaneously at the 8 weeks follow-up visit. A small scar (2 mm) was observed on one RF+ PDL test site at the 4 weeks follow-up visit on one subject. The scar was subsequently treated by PDL alone and had resolved completely at the 8 weeks follow-up. Pain was quantified using a scale of 1-10 (with 10 being the worst pain) by the subject immediately after treatment using each modality. There remains a trend of more pain reported in the RF+PDL treated sites (6.7) vs. the PDL site (5.5). Student's t-tests showed that the treatment efficacy with the addition of RF pre-heating, namely RF+PDL, did not result in a statistically significant improved PWS blanching response as compared to PDL alone. The subjects enrolled in this study had PWS birthmarks that were highly resistant to previous PDL treatment. With the exception of one subject, all other enrolled subjects had PWS that had undergone numerous PDL treatment sessions. Those subject's PWS had reached a response plateau to in response to PDL treatment and become unresponsive to continued PDL treatments. Unfortunately, the addition of RF pre-heating, namely RF+PDL, did not result in a statistically significant improved PWS blanching response as compared to PDL alone.

- **Internal and External Audits**

a. Did any internal audits occur since the last IRB review?
( ) YES (•) NO

If yes, please describe briefly the audit finding(s) here and indicate how the issues were resolved:

b. Did any external audits occur since the last IRB review?
○ YES ◉ NO

If yes, please indicate what entity performed the audit and describe briefly the audit finding(s) here. Be sure to indicate how the issues were resolved:

c. Was the IRB notified of the external audit?
○ YES ○ NO ◉ No external audit performed

If no, please indicate why not:

- **Publications**
  Please provide citations for any publication(s) or presentation(s) derived from this study since the last IRB review. If there have been no publications, please state such.

  None

- Certification of the Investigator's Intent to Close the Study

Upon submission of this final closing report for protocol HS# 2012-9092, I hereby certify my intent to close the study and I affirm that all the information contained herein is true and accurate to the best of my knowledge. If additional significant information about the safety or welfare of study participants should become available after study closure, I will forward it to the IRB promptly for review and inclusion in the protocol record.

☑ I certify.

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IRB CHAIR SIGNATURE DATE