



PAIN RELIEF WITHOUT DRUGS

Recruiting study sites for IRB studies:

1. Microcurrent for Reducing Pain and size related to chronic wounds

Purpose of the studies: US IRB study using microcurrent therapy for

- Pain relief for reducing opioid use
- Pain relief for covered open wounds
- Reducing wound size in chronic wounds

This is a validation study modeled after the 100-patient case series in Malaysia which was a joint effort where the

- Hospital provided facilities, patients with chronic wounds, standard of care therapy and staff to provide Avazzia microcurrent.
- Avazzia provided devices, paid a nurse to train hospital staff, patient training, document control
- Therapy applied before dressing removal and changes to dressings and also applied at home by participants.
- The hospital or hospital staff was not paid by Avazzia

Result was cost-effective study in a premier government hospital.

Malaysia 100-patient case series was presented at the North Borneo Wound Conference, Magellan Sutura Harbour, Kota Kinabalu, Sabah, 20 August, 2016 by Dr. Harikrishna K.R. Nair SIS KMN, MD, OSH, OHD, CMIA, Wound Care Unit, Department of Internal Medicine, Kuala Lumpur Hospital.

Data presented has not been reviewed or evaluated by the US FDA. Devices are not intended for the diagnosis or treatment of disease condition.

Avazzia devices are US FDA cleared as TENS For symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain.

Application for Principal Investigator and/or study site for Proposed IRB studies:

Name of person completing this form: _____

Name of clinic: _____

Address, city, state, zip: _____

Name of Primary contact for the study: _____

Name of Potential Principal Investigator for: _____

Phone: _____ email: _____

Have you ever done a study before? ___ yes ___ no

About how many patients with **chronic Pain** are seen at this clinic per month?

- ___ less than 10
- ___ between 10 and 50
- ___ between 50 and 100
- ___ over 100

About how many patients with **chronic (more than 30 days old) wounds** are seen at this clinic per month?

- ___ less than 10
- ___ between 10 and 50
- ___ between 50 and 100
- ___ over 100

What type of wounds do you see the most of

- ___ diabetic ulcers
- ___ pressure wounds
- ___ burns
- ___ injuries
- ___ other: _____

Are you interested in (check all that apply)

Pain Study:

- ___ Phase 1, single site, unblinded, validation case series study with patients with documented chronic pain and opioid use
- ___ Phase 2, multi-site, double blinded study
- ___ not sure

Wound study:

- ___ Phase 1, unblinded, validation clinical study with patients with documented chronic wounds to confirm Malaysia results
- ___ Phase 2, multi-site, double blinded study
- ___ not sure

Estimated number of participants appropriate for inclusion within 3-month study time frame: (ie. How many participants might be interested in a 3-month time frame?) _____

What electronic medical records or health record system is used at this clinic? _____

Does this clinic perform HBOT? ___ yes ___ no

Are photos taken at every wound dressing change as a matter of standard practice? ___ yes ___ no

What method of pain relief is typically used before removing wound dressings? _____

How often do patients with chronic wounds have their dressings changed typically? _____

Do patients come in to the clinic for dressing changes, or are they seen by home health care? Please explain:

Would it be more efficient to share patient information at appointments such as wound photo, BP, temperature, heart rate and other notes, or do you prefer that data is recorded once in patient records using standard practice, and basic information is repeated for study records? Write in preference.

Patients with chronic pain are: (check one)

- treated at clinic
- referred to a Pain Management Clinic

Funding:

- Yes, we are interested in cost-sharing study where Avazzia provides a nurse or other trained study personnel?
- other; contact our clinic for more information

Avazzia manufactures microcurrent devices for pain relief which could be useful.

Avazzia is also developing an IRB study for pain relief therapy to determine reduction of opioid use if any, and a study for pain relief and adjunctive care for covered chronic wounds.

Please express clinic's interests (one or both):

- Yes, we are interested in Avazzia providing staff training for using microcurrent devices for pain relief.
- No, we are not interested in Avazzia providing staff training to help with this study.
- Yes, we are interested in meeting to discuss roles, responsibilities and funding for a study.

Suggest three dates/times for follow up phone calls by the study sponsor to review and discuss this study. We will try to accommodate your schedule.

1. _____
2. _____
3. _____