

Proposed Protocol to Study Hair Growth and Skin Rejuvenation with MedTec Magnetic Resonance

Revision 2, J. Boll

4/13/17

Overview: The following draft protocol is designed towards an investigation of inducing hair growth with magnetic fields. The device to be investigated is used primarily for the orthopedic specialty, but anecdotal evidence suggests it has the capability of stimulating hair growth (scalp, eyebrows and eyelashes) as well as revitalizing skin.

The study is recommended to be limited to a small population ($n \approx 10$) and represent a best effort, providing a limited understanding and help guide future studies. Unless there is some unexpected flaw to the study design, there would be no interest on the part of Cynosure to continue if no improvement is observed in this first study.

Device Description: Patients would be subjected to low level magnetic fields by being seated in a booth where there would be no contact of the device to the head and neck. The patient feels no sensation during the exposure and is free to limited head movements within the booth. The exposures are 60 minutes long and require no supervision as there is no danger or safety concerns regarding the exposure. Once the patient is seated and prepared, the operator can leave the room and come back as needed or when the exposure is complete.

The magnetic field is tuned for optimum effect and it is the recommendation of MedTec to enhance the coupling with a gel, hyaluronan. Why gel? Hyaluronan (acid) binds with water and the MBST technology uses the water (hydrogen protons as carrier) to induce the energy into the cells. The effect with hyaluronan gel should be enhanced and there is no reason to think it will impede.

Sample Protocol: Patient recruitment shall be 12 patients with the objective being 10 patients completing the series of exposures. The population of 10-12 persons shall be treated with program A (a best guess at the output parameters which generated interest in the previous trials where hair growth was observed). Each patient will apply gel 2 days before the first treatment hour. The test person shall apply it every day until the observation period is completed.

A small area (e.g. 1 square centimeter) of the head hair shall be shaved and the number of hairs shall be counted in this area before the first treatment hour. A high resolution macro photo of the area and a scale will serve as the baseline. The location of the shaved portion will be registered to anatomical landmarks so it can be easily located at the completion of the study.

In addition to the hair count of the small area, a full record of the face will be made with a Canfield camera system. This will record the hair line, eyelashes and eyebrows as well as any changes in texture to the skin. The skin and eyelashes must be cleaned and free of make-up.

Additionally, photographs of the top of the head will be required to assess any changes seen with regard to hair growth in this area. A patient and physician assessment form should also be completed at the end of the study.

The treatment regimen is 10 treatments, 1 hour in duration, one per day, 5 per week, for two weeks.

After 6 weeks and 12 weeks from completion of the 10 treatment hours, the number of hairs in the respective area shall be counted again.

Responsibilities:

MedTec will provide:

- 1) Collaborative protocol writing assistance
- 2) The MBST device(s)
- 3) Treatment chip cards which allow the unit to be activated
- 4) Macro and general photographic equipment
- 5) Facility space to treat patients
- 6) Personnel to recruit, manage schedules and follow-up with patients
- 7) Data and reports

Cynosure will provide:

- 1) Collaborative protocol writing assistance
- 2) Coordination, installation, training and rental of Canfield camera system
- 3) Scheduling, reimbursement and communications with principal investigator, Dr. Christine Dierickx

Next Steps

- 1) Dr. Dierickx, Cynosure and MedTec will iteratively modify the protocol for mutual agreement.
- 2) Dr. Dierickx will visit MedTec to acquaint herself with the device and meet the scientific team.
- 3) Based on her visit, a final protocol is signed off and recruitment and scheduling can begin.

Cynosure – hair study (pilot study resp. treatment trials) – design proposals

4 groups of 10 persons

MedTec provides

- the device (s)

- following treatment chip cards:

20 treatment chip cards with a treatment program (A) of 10 treatment hours each

20 treatment chip cards with a different treatment program (B) of 10 treatment hours each

- gel with hyaluronan (acid)

Why gel?

As hyaluronan (acid) is binding water and the MBST technology uses the water (hydrogen protons as carrier) to induce the energy into the cells the effect with hyaluronan gel should be better. If significantly better will show the study results.

Test persons divided in 4 groups:

- 10 persons treated with program A

- 10 persons treated with program B

- 10 persons treated with program A plus applying the gel 2 days before the first treatment hour. The test person shall apply it every day until the observation period is completed.

- 10 persons treated with program B plus applying the gel 2 days before the first treatment hour. The test person shall apply it every day until the observation period is completed.

A certain small area (e.g. 1 square centimeter) of the head hair shall be shaved and the number of hairs shall be counted in this area before the first treatment hour. You may use a high resolution camera.

Within 2 weeks the 10 treatment hours of 1 per day (5 per week) shall be completed.

6 weeks and 12 weeks after completion of the 10 treatment hours the number of hairs in the respective area shall be counted again.

Additional you may measure the ATP and Oxygen concentrations in the cells.

You may observe the development of the skin of the test persons:

- measure the wrinkles (length and deepness)

- observe the appearance/the look (photographs with always the same camera and the same light situation)

