A Study of Revian Red All LED cap as a novel treatment for Central Centrifugal Cicatricial Alopecia

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Wake Forest™
School of Medicine

Department/Section of Dermatology

A Study of Revian Red All LED cap as a novel treatment for Central Centrifugal Cicatricial Alopecia (CCCA)

Informed Consent Form to Participate in Research

Amy McMichael, M.D, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to determine if the Revian Red All LED cap is an effective treatment for Central Centrifugal Cicatricial Alopecia (CCCA). You are invited to be in this study because you are an African-American woman who is currently receiving treatment for a form of hair loss called Central Centrifugal Cicatricial Alopecia (CCCA). Your participation in this research will involve 4 visits and last about 6 months.

Participation in this study will involve using the Revian Red All LED cap once daily for 10 minutes for a total of 6 months. You will have a visit scheduled at the start of the study and every 2 months until the study is completed (4 visits total). All research studies involve some risks. A risk to this study that you should be aware of is mild discomfort, skin irritation, or temporary redness at the site of the scalp where the cap is applied. However, most patients do not experience any side effects. You may or may not benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include prescription topical and/or oral medications. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Amy McMichael, MD, Principal Investigator. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted]

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are an African-American woman who is currently receiving treatment for a form of hair loss called Central Centrifugal Cicatricial Alopecia (CCCA). Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

WFU School of Medicine
Institutional Review Board
IRB Number: IRB00094234
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The purpose of this research study is to determine if the Revian Red All LED cap is an effective treatment for central centrifugal cicatricial alopecia (CCCA).

The Revian Red All LED cap is FDA approved and available over the counter for treatment and promotion of hair growth for androgenetic alopecia in males and females.

How Many People Will Take Part in the Study?

Approximately 23 people will take part in this study. This study is being done at this site, the Wake Forest Baptist Health Department of Dermatology in Winston Salem, NC.

What Is Involved in the Study?

You will be asked to use the Revian Red All LED cap once daily for 10 minutes for a total of 6 months. To use the cap, you will connect the wireless Revian Red All LED cap to a Smart App on your phone using Bluetooth. The Smart App will help you track your 10 minute daily use of the cap. The Smart App will give daily reminders to use the cap and provide a 10 minute timer when using the cap.

You will have a visit scheduled at the start of the study and every 2 months until the study is completed (4 visits total).

You will be asked to complete four questionnaires about your hair and CCCA's impact on your quality of life. Two questionnaires will be completed at the initial visit at the start of the study. Two questionnaires will be completed at the final follow up visit at the end of the study. You will have photographs taken of your scalp hair. Photographs of your scalp hair will be taken at the initial visit before starting the study and at each visit every 2 months until the study is completed for 6 months (4 photographs total). You will also have high-quality, standardized facial images using the Visia Skin Analysis system at your first visit, as well as your last visit. You will also be called once every two weeks to verbally confirm consistent use of the cap.

If you take part in this study, you will have the following tests and procedures:

- Standardized hair questionnaire
- Standardized quality of life questionnaire
- Review of your medical record
- Photographs taken of your scalp hair

As part of this research study, you will be photographed. This is being done to document the degree of hair loss you have at the time of the study and assess regrowth. You understand that you may request the photography be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the photograph(s) before it is used. You should also understand that you will not be able to inspect, review, or approve the photograph(s) (including articles containing such) before they are used in this study. At the end of this document you can select your preferences about the use of photography.

How Long Will I Be in the Study?

You will be in the study for 6 months. During that time, all visits, questionnaires, and photographs will be collected. These interventions should not exceed 30-60 minutes. There will be no long-term follow-up required of you. You will not be required to return the cap following study completion.

What Are the Risks of the Study?

Possible risks include mild discomfort, skin irritation, or temporary redness at the site of the scalp where the cap is applied. However, most patients do not experience any side effects. There is a slight risk of a breach of

confidentiality. We will do our best to protect your confidential information. Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Are There Benefits to Taking Part in the Study?

You may or may not receive any direct benefit from participating in this study. You may have improvement of your hair loss, regrowth of hair, or stabilization of hair loss. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be: a better understanding of alternative treatments for hair loss with laser therapy. We hope this information could lead to the development of new treatments in the future.

What Other Choices Are There?

Your alternative is to not participate in this study. You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options:

- Prescription topical medications
- Prescription oral medications
- Procedural therapies
- Over the counter treatments

Will Your Research Records be Confidential?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety and/or effectiveness of the Revian Red All LED cap; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

What About My Health Information?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: information about your hair and CCCA's impact on your quality of life.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer. Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research.
2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state law.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire and any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Amy McMichael, M.D. that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Amy McMichael, M.D.
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about that research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist

Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of the study.

Furthermore, you will be asked to download a SmartApp to your phone. You will have access to your user profile, compliance data, treatment history, photo journals, FAQs and instructions for use within the App. At any point, you can contact the Customer Support Team of Revian with questions or troubleshooting technical issues, set treatment reminders or add a 2nd user if you wish. Revian will only have access to information that you, the user, rovides to them via email. This will be entered directly into a form during registration or through the support ticket system, including name of user, gender, email, birth year and device type. Revian will also have access to the photo journal photos, internal temperature recordings of the cap at every minute of treatment (for safety reasons), user compliance data and treatment start and stop times.

Revian does not sell, rent or provide this information to anyone beyond the organization, with the exception of customers purchasing through an Affiliate referral code. This does not apply to you through this study. In addition, users can contact Revian at any time to see what data they have about your, if any, change or correct data, and ask for the data stored to be deleted. A full privacy policy for Revian can be found at https://revian.com/privacy-policy/

What Are the Costs?

There are no costs to you for taking part in this study. All study costs, including any procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

Will You Be Paid for Participating?

If you participate in this study, there is no payment for participation.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

Who is Sponsoring this Study?

This study is being sponsored by the Department of Dermatology at Wake Forest Baptist Medical Center. The sponsor is providing money or other support to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor.

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because the study has stopped recruiting new participants or because you have another condition that makes it more difficult for us to study CCCA. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Amy McMichael at [redacted] or after hours through the hospital operator at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

I consent to be part of this study.

Please choose one of the following regarding the use and disclosure of the photograph(s) used in this research study:

_____ I would like the photograph(s) of me to be destroyed once their use in this study is finished.

____ The photograph(s) of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

Subject Name (Printed):_____
Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____
Person Obtaining Consent:_____ Date:_____ Time:_____ am pm