CONSENT FORM

Safety and Efficacy of Combined Restylane® and Triamcinolone acteonide Injections for the Treatment of Alopecia Areata

Sponsor:	Medicis Pharmaceutical Corporation
Site:	Department of Dermatology University of Minnesota
Principal Investigator:	Maria Hordinsky, M.D.
Study Team:	Charles Crutchfield III, M.D. Ronda Farah, M.D. Heather Bemmels, M.S., C.G.C.

You are invited to participate in a research study to examine whether the treatment you will be receiving for alopecia areata has an impact hair growth. You are being asked to participate in the study because you have expressed interest in treatments for alopecia areata. Your participation is completely voluntary.

Before agreeing to participate in this study, it is important that you read this consent form. This form may contain words that have not been explained well enough. Please ask one of the study team to explain any information that is not clear. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

This study is being conducted by Maria Hordinsky, M.D., Department of Dermatology, University of Minnesota. Other members of the study team are Dr. Ronda Farah, Dr. Charles Crutchfield, and Heather Bemmels, M.S., C.G.C., Clinical Research Coordinator in the Department of Dermatology at the University of Minnesota.

Why is this study being done?

The purpose of the study is to see whether treating alopecia areata with injections of the corticosteroid, triamcinolone acetonide, with Restylane®, a dermal filler, has an impact on hair growth.

Corticosteroids are powerful anti-inflammatory drugs similar to a natural hormone called cortisol that is produced by the adrenal glands. Because corticosteroids suppress the immune system, they are often used in the treatment of various autoimmune diseases, including alopecia areata. Injections of triamcinolone acetonide given directly into hairless patches on the scalp and sometimes the brow and beard areas are effective in halting alopecia areata and inducing hair growth in most people. The drug removes the

confused immune cells and allows the hair to grow. It usually takes about 1 or 2 months for new hair growth to become visible.

Restylane®, also known as Hyaluronic acid, is currently approved for use as a dermal filler for wrinkles of the face. It enhances the movement of cells involved in wound healing and provides a favorable environment for cells of the repair process to migrate.

The purpose of this study is to examine whether there is an increase in hair regrowth in patients with alopecia areata when intralesional injections of Restylane® are given with triamcinolcone acetonide when compared to intralesional injections of triamcinolone acetonide alone. No studies have been done to evaluate the effectiveness of combined Restylane® and triamcinolone acetonide intralesional injections.

What is involved in the study?

If you agree to participate in this study, you will be asked about your medical history and other drugs that you are taking to make sure you are eligible for the study. The study will involve receiving intralesional injections of Restylane® and triamcinolcone acetonide at the bald areas of your scalp on one side. Triamcinolone acetonide will be injected alone to the bald areas on the other half of the scalp. Non- identifying photographs of the scalp will be taken at the first appointment and then at the second and third appointments to document changes in hair growth. Because the drugs in this study may affect a fetus, pregnant women may not participate in this study. If you are a female of child-bearing potential (i.e., you have had your first menstrual period and have not yet reached menopause), a urine test will be done at the initial visit and prior to the second injection to make sure you are not pregnant.

How long will the study last?

The study will last about 12 weeks. At the first and second visits you will receive intralesional injections. The visit will be scheduled approximately 6 weeks apart. Photographs will be taken at both visits.

What are the possible risks?

The risks of participating in the study include:

Intralesional injections: Risks associated with the intralesional triamcinolone acetonide injections include dizziness, bleeding, bruising, pain, discoloration, inflammation, allergic reaction, death of tissue (necrosis), tenderness and, rarely, fainting, acne or the possibility of developing an infection at the injection site.

In studies involving the use of Restylane® as a dermal filler for facial wrinkles infrequent reports of the following were made to the manufacturer: inflicted injury, stuffy nose (sinusitis), upper respiratory tract infection, acne, back pain, depression, tooth disorder, bronchitis, pneumonia, rash (contact dermatitis), allergic reaction, joint pain (arthralgia),

osteoporosis, headache, migraine, herpes simplex, high cholesterol, involuntary leakage of urine (urinary incontinence), , seasonal allergy, reaction to make-up around the eye.

Are there any potential benefits?

There are no direct health benefits to you from participating in this study, other than the possibility of hair regrowth. It is possible that the information gained from your participation may help others with alopecia areata.

What other options are there?

You do not need to participate in this study to receive treatment for your alopecia areata. Your doctor will discuss the various treatment options with you. You may choose not to participate in the study and still receive treatment with intralesional triamcinolone acetonide.

What are the costs?

You will not be charged for procedures or clinic visits related to this research. Triamcinolone acetonide and Restylane® will be provided free of charge while you are in the study.

What will happen if there is a research-related injury?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study physicians know right away.

What about confidentiality?

The records and photography of this study will be kept private. In any publications or presentations, you will not be identified by name or other recognizable way on any records, results or publications relating to the study.

Participation and results in this study may be recorded in your medical record.

Your information may be transmitted and/or reviewed by University of Minnesota (UM), University of Minnesota Physicians (UMP) and University of Minnesota Medical Center (UMMC) personnel who monitor research and UM, UMP and Medical Center personnel who need access to the information to complete the clinical trial.

Your protected health information (PHI) created or received for the purposes of this study is protected under the federal regulation known as HIPAA. You will be asked to review and sign a separate HIPAA authorization concerning the use of this information.

To these extents, confidentiality is not absolute.

What are your rights as a research subject?

Your participation in this study is entirely voluntary and you have the right to choose not to participate. Your decision whether or not to participate in this study, or to withdraw from the study, will not affect any subsequent treatment by your doctor or this clinic, in any way and will not involve any penalty or loss of benefits to which you are otherwise entitled.

The study team can stop your participation in the study at any time without your consent for any reason. You also have the right to withdraw from the study **at any time**, even after signing the consent form, without giving a reason.

If you withdraw voluntarily from the study or are taken out of the study, you may be asked questions about your experience in the study. You also may be asked to have laboratory tests and physical examinations, as the doctor considers necessary.

The study doctors will notify you if there are new findings about triamcinolone acetonide or Restylane® that might affect your willingness to continue to be in the study, or that could affect your health either during or after the study.

You may ask any questions you have now, or if you have questions later, you may contact them at 612-625-7420.
If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), you are encouraged to contact the Fairview Research Helpline at telephone number 612-672-7692 or toll free at 866-508-6961. You may also contact this office in writing or in person at *Fairview Research Administration, 2433 Energy Park Drive, St. Paul, MN 55108*.

You will be given a copy of this form to keep for your records.

Statement of Consent

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

_____
Subject's Name (Print)

_____
Subject's Signature

_____
Date of Signature

_____
Name of person conducting consent process (Print)

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Signature of person conducting consent

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Date of Signature