Stem Cell Educator Therapy in Alopecia Areata

ClinicalTrials.gov Identifier: NCT01673789

Recruitment Status : Unknown
Verified August 2012 by Throne Biotechnologies Inc..
Recruitment status was: Recruiting
First Posted : August 28, 2012
Last Update Posted : August 28, 2012

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Sponsor:
Throne Biotechnologies Inc.

Collaborator:
The First Hospital of Hebei Medical University

Information provided by (Responsible Party):
Throne Biotechnologies Inc.

Study Details | Tabular View | Results Submitted | Disclaimer | How to Read a Study Record

Study Description

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Brief Summary:
Alopecia Areata (AA) is one of the most common T cell-mediated autoimmune diseases, leading to the chronic and relapsing hair loss. The prevalence of AA worldwide is 0.1 to 0.2%, affecting an estimated 5.3 million people in the United States. To date, the clinical therapies are limited and disappointed for the treatment of AA. Alternative approaches are needed. Increasing evidence demonstrates that stem cells possess the function of immune modulation. We established the Stem Cell Educator therapy by using cord blood-derived multipotent stem cells (CB-SCs)(Zhao Y, et al. BMC Medicine 2012). A closed-loop system that circulates a patient's blood through a blood cell separator, briefly co-cultures the patient's lymphocytes with adherent CB-SCs in vitro, and returns the educated lymphocytes (but not the CB-SCs) to the patient's circulation. Our clinical trial reveals that a single treatment with the Stem Cell Educator provides lasting reversal of autoimmunity that allows regeneration of islet beta cells and improvement of metabolic control in subjects with long-standing type 1 diabetes (T1D), which is another most common T cell-mediated autoimmune disorder in the United States. Here, we develop and explore the therapeutic effectiveness of Stem Cell Educator therapy in AA patients.

Condition or disease	Intervention/treatment	Phase
Alopecia Areata	Device: Stem Cell Educator	Phase 1 Phase 2

Detailed Description:
A 16-gauge IV needle is placed in the left (or right) median cubital vein, and the patient's blood is passed through a Blood Cell Separator MCS+ (Haemonetics®, Braintree, MA) at 35 mL/min for 6 to 7 hours to isolate lymphocytes in accordance with the manufacturer's recommended protocol. The collected lymphocytes are transferred into the device for exposure to allogeneic CB-SCs (or process control without CB-SCs), and other blood components are returned to the patient. After 2 to 3 hours in the device, lymphocytes are returned to the patient's circulation via a dorsal vein in the hand under gravity flow control (2 to 3 mL/min) with physiological saline. Approximately 10,000 mL of blood is processed during the procedure resulting in approximately two repeated educations for the lymphocyte fraction. Patients are hospitalized for two days to monitor temperature and conduct routine laboratory blood tests for adverse reactions following treatment. Follow-up visits are scheduled 4, 12, 24, 40, and 54 weeks after treatment for clinical assessments and laboratory tests

Study Design

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Study Type :
Interventional (Clinical Trial)

Estimated Enrollment :
30 participants

Allocation:

N/A

Intervention Model:

Single Group Assignment

Masking:

None (Open Label)

Primary Purpose:

Treatment

Official Title:

Phase 1/Phase 2 Study of Stem Cell Educator Therapy in Alopecia Areata

Study Start Date :

August 2012

Estimated Primary Completion Date :

July 2013

Estimated Study Completion Date :

July 2013

Resource links provided by the National Library of Medicine

MedlinePlus Genetics related topics: Alopecia areata

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Stem Cell Educator The collected lymphocytes are transferred into the device for exposure to CB-SCs, and other blood components are automatically returned to the patient. The Stem Cell Educator functions as part of a closed-loop system that circulates a patient's blood through a blood cell separator, briefly co-cultures the patient's lymphocytes with CB-SCs in vitro, and returns the educated lymphocytes to the patient's circulation. CB-SCs tightly attached to interior surfaces in the device, and only the CB-	Device: Stem Cell Educator For the treatment, commonly the left (or right) median cubital vein, a patient's blood is passed through a Blood Cell Separator that isolates the lymphocytes from the blood according to the recommended protocol by manufacture; consequently, the collected lymphocytes were transferred into the Stem Cell Educator and treated by CB-SC; after that, the educated cells return the blood back to the patient via a dorsal vein of hand. During the MCS+ collection, the

Arm	Intervention/treatment
SC-educated autologous lymphocytes are returned to the subjects. The Stem Cell Educator therapy requires only two venipunctures with minimal pain, and does not introduce stem cells or reagents into patients.	whole blood flow rate was maintained at 35 mL/min. The whole procedure was scheduled for 8 ~ 9 hrs.

Outcome Measures

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Primary Outcome Measures :

1. Feasibility and efficacy of Stem Cell Educator therapy in AA [Time Frame: 1 year]

   The primary study end points are 1) feasibility of the Stem Cell Educator therapy in AA, 2) preliminary evaluation of the efficacy of the therapy for improving hire grow through a year.

Secondary Outcome Measures :

1. The efficacy of Stem Cell Educator therapy in modulating autoimmunity [Time Frame: 1 year]

   The secondary study end point was evidence of the efficacy of the therapy in modulating autoimmunity. Baseline blood samples are collected prior to Stem Cell Educator therapy.

Eligibility Criteria

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Information from the National Library of Medicine NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:

18 Years to 65 Years (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

No

Criteria

Inclusion Criteria:

- Patients are screened for enrollment in the study if both clinical signs and laboratory tests meet the diagnosis standards recommended by the National Alopecia Areata Foundation (www.naaf.org).

Exclusion Criteria:

- Exclusion criteria are any clinically significant diseases in liver, kidney, and heart. Additional exclusion criteria are no pregnancy, no immunosuppressive medication, no viral diseases or diseases associated with immunodeficiency.

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT01673789***

Locations

China, Hebei

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Investigators

Study Chair: Yong Zhao, MD, PhD Throne Biotechnologies Inc.

More Information

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Additional Information:

Tianhe Stem Cell Biotechnologies Inc.

Publications:

Zhao Y, Jiang Z, Zhao T, Ye M, Hu C, Yin Z, Li H, Zhang Y, Diao Y, Li Y, Chen Y, Sun X, Fisk MB, Skidgel R, Holterman M, Prabhakar B, Mazzone T. Reversal of type 1 diabetes via islet beta cell regeneration following immune modulation by cord blood-derived multipotent stem cells. BMC Med. 2012 Jan 10;10:3. doi: 10.1186/1741-7015-10-3.

Zhao Y. Stem cell educator therapy and induction of immune balance. Curr Diab Rep. 2012 Oct;12(5):517-23. doi: 10.1007/s11892-012-0308-1.

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Li Y, Yan B, Wang H, Li H, Li Q, Zhao D, Chen Y, Zhang Y, Li W, Zhang J, Wang S, Shen J, Li Y, Guindi E, Zhao Y. Hair regrowth in alopecia areata patients following Stem Cell Educator therapy. BMC Med. 2015 Apr 20;13:87. doi: 10.1186/s12916-015-0331-6.

Responsible Party:

Throne Biotechnologies Inc.

ClinicalTrials.gov Identifier:

NCT01673789 History of Changes

Other Study ID Numbers:

2012-TH01

First Posted:

August 28, 2012 Key Record Dates

Last Update Posted:

August 28, 2012

Last Verified:

August 2012

Keywords provided by Throne Biotechnologies Inc.:

Stem Cell Educator
Cord blood stem cells
Immune modulation
Alopecia Areata

Additional relevant MeSH terms:

Alopecia

Alopecia Areata

Hypotrichosis

Hair Diseases

Skin Diseases

Pathological Conditions, Anatomical