Proposed HairCell Phase I Safety and Efficacy Pilot Clinical Trial Study Design

Trial ID	TBD
Ethics application status	Pending
Date submitted	Not Yet Submitted
Date registered	Not Yet Registered
Type of registration	Prospectively registered

Titles & IDs

Public title	A Single-Center, Randomized, Double-Blind, Placebo Controlled Study of the Safety, Tolerability and Pharmacokinetics of the HairCell Hair Regeneration Stimulator, HC-15 stem cell based composition and Micro Infusion Pump
Scientific title	A Single-Center, Randomized, Double-Blind, Placebo Controlled Study of the Safety, Tolerability and Pharmacokinetics of the HairCell Hair Regeneration Stimulator, HC-15 stem cell based composition and Micro Infusion Pump
Secondary ID [1]	
Universal Trial Number (UTN)	TBD
Trial acronym	

Health condition

Health condition(s) or problem(s) studied:	
Androgenetic Alopecia	
Condition category	**Condition code**

Skin	Dermatological conditions

Intervention/exposure

Study type	Interventional
Description of intervention(s) / exposure	The study device is a bioelectric stimulator combined with a micro infusion pump connected to a delivery system head cap. The regeneration stimulator controls release of SDF-1 (a stem cell homing factor), IGF-1, HGF, EEGF, Folllistatin, Tropoelastin, eNOS and VEGF. The micro infusion pump is used in severe hair loss cases and is re-filled weekly with our proprietary HC-15 hair regeneration composition comprised of stem cells, endothelial progenitor cells, human growth hormone, nutrient hydrogel, hair growth topical compositions, Micro RNAs, hair scalp matrix, SDF-1, Follistatin, EGF and IGF-1. The dosages of bioelectric stimulator will be increase from 20 minutes, to 40 minutes to 60 minutes per day. The dosage of HC-15 Hair Regeneration Composition will be increased from 1 ml weekly, to 1.5 mls to 2 mls. Administration of the study bioelectric stimulation will be once daily for 14 days at the study clinic; study micro infusion HC-15 composition is slowly infused drug weekly to the scalp. There are three cohorts of 10 participants. Cohort 1 will be administered the 20 minutes bioelectric stimulation daily and 1ml HC-15 composition infusion weekly, Cohort 2 will be administered 40 minutes bioelectric stimulation daily and 1.5 mls HC-15 composition infusion weekly and Cohort 3 will be administered the 60 minutes of bioelectric stimulation daily and 2mls of HC-15 composition weekly. Participants will complete a series of tests prior to the start of the study. During the study the participants' scalp will be assessed by the study doctor on a daily basis and prior to administration of the study drug. Hair growth assessments will also be completed by the study doctor and the participant 1 day following the completion of the treatment and 14 days following completion of the treatment.
Intervention code [1]	Treatment: Bioelectric stimulation daily and biological stem cell based composition infusion weekly
Comparator / control treatment	The placebo is a topical solution (polyethylene glycol)
Control group	Placebo

Outcomes

Primary outcome [1]	To characterize the safety and tolerability of HairCell bioelectric stimulation 20, 40 and 60 minutes daily and HC-15 compositio

	n infusion weekly applied to the scalp of male subjects with Androgenetic Alopecia. This is assessed by the following: 1. Collection of adverse events following the first administration of the study drug and up until Day 28 (14 days post the final administration of the study drug); 2. Non fasting clinical laboratory analysis of Chemistry, Haematology and urinalysis during the screening visit and on the 14th day of treatment and 14 days following the end of the treatment; 3. Collection of Vital Signs each day of treatment; 4. Daily assessment of the participants' scalp each day prior to treatment. 5. ECG at screening, Day 1 and Day 14, prior to treatment and 4 hours after treatment.
Timepoint [1]	Day 1 to Day 14.
Secondary outcome [1]	To characterize the pharmacokinetics (PK) of HairCell bioelectric stimulation and HC-15 composition applied to the scalp of male subjects with AGA
Timepoint [1]	PK samples will be taken on Day 1 and 2 and on Day 14 and 15 at the following timepoints: Pre dose; and at 1,2,4,6,9,12 and 24 hours post dose.
Secondary outcome [2]	To assess hair growth and quality based upon questionnaires completed by the physician and subject.
Timepoint [2]	Hair growth will be assessed by the PI using an 'Investigator assessment scale' at Day 15 and Day 28. Hair growth will be assessed by the subject using a 'subject assessment of hair growth' questionnaire at Day 15 and Day 28. Scalp photography will be taken prior to study drug administration and then again at Day 15 and 28.

Eligibility

Key inclusion criteria	Males between 18 and 60 years of age, inclusive Diagnosed with androgenetic (AGA) alopecia with a Norwood-Hamilton Classification score of 4, 5, 6 or 7. In good general health Willing and able to attend study visits Willing to maintain same hair style for the duration of the study Willing to use a sponsor supplied shampoo and conditioner for the duration of the study Able to comprehend and willing to sign an informed consent form
Minimum age	18 Years
Maximum age	60 Years

Gender	Males
Can healthy volunteers participate?	Yes
Key exclusion criteria	Clinical diagnosis of alopecia areata or other non-AGA form o f alopecia. Scalp hair loss, on the treatment area, due to disease, injury o r medical therapy. Males who are sexually active and have a partner that is capa ble of becoming pregnant, neither of which have had surgery to become sterilized, who are not using an effective method of birth control (e.g., surgically implanted hormonal therapy, i ntrauterine devices or oral birth control with barrier method). Current skin disease (e.g., psoriasis, atopic dermatitis, skin ca ncer, eczema, sun damage, seborrheic dermatitis), cuts and o r abrasions on the scalp or condition (e.g., sunburn, tattoos) o n the treatment area that, in the opinion of the investigator, m ight put the subject at risk or interfere with the study conduct or evaluations. History of surgical correction of hair loss on the scalp. Use of finasteride or dutasteride within the 12 weeks prior to t he Screening Visit. Use of minoxidil within the 12 weeks prior to the Screening Vi sit. Use of anti-androgenic therapies (e.g., spironolactone, flutami de, cyperoterone acetate, cimetidine) within 12 weeks prior to the Screening Visit. Use of any scalp hair growth products within the 12 weeks pri or to the Screening Visit. History of hair transplants. Current use of an occlusive wig, hair extensions or hair weave s History of hypersensitivity or allergies to any ingredient of the study medications. Participation in any other investigational drug trial in which ad ministration of an investigational study medication occurred within 30 days prior to the Screening Visit. Poor peripheral venous access. Subjects with a history of clinically significant cardiac arrhyth mia as determined by the principal investigator. Subjects with clinically significant findings from medical histo ry, clinical laboratory tests, ECG and vital signs that, in the opi nion of the investigator, could interfere with the objectives of the study or put the subject at risk.

Study design

Purpose of the study	Treatment

Allocation to intervention	Randomised controlled trial
Procedure for enrolling a subject and allocating the treatment (allocation concealment procedures)	Subjects will attend a screening visit. If they meet the inclus ion criteria and none of the exclusion criteria then they will be deemed by the investigator to be eligible to enter the st udy. The investigator and study staff with the exception of t he pharmacist are blinded to the study treatment. A rando mization list computer generated and is provided by the sp onsor to the pharmacist who is unblinded. Blinded study pe rsonnel will assign subject number sequentially.
Methods used to generate the sequence in which subjects will be randomised (sequence generation)	
Masking / blinding	Blinded (masking used)
Who is / are masked / blinded?	The people receiving the treatment/s The people administering the treatment/s The people assessing the outcomes The people analysing the results/data
Intervention assignment	Parallel
Other design features	
Phase	Phase 1
Type of endpoint(s)	Safety

Recruitment

Anticipated date of first participant enrolment	08/01/2016
Actual date of first participant enrolment	TBF
Anticipated date last participant enrolled	10/01/2016
Actual date last participant enrolled	TBD
Anticipated date of last data collection	
Actual date of last data collection	
Target sample size	30
Actual sample size	
Recruitment status	Not Yet Started

Recruitment in Australia	
Recruitment state(s)	QLD
Recruitment postcode(s) [1]	

Funding & Sponsors

Funding source category [1]	Commercial sector/Industry
Name [1]	HairCell a Leonhardt Ventures Co.
Address [1]	1531 6th Street, Unit 401 Santa Monica, CA 90401
Country [1]	United States of America
Primary sponsor type	Commercial sector/Industry
Name	HairCell a Leonhardt Ventures Co.
Address	1531 6th Street, Unit 401 Santa Monica, CA 90401
Country	United States of America
Secondary sponsor category [1]	Commercial sector/Industry
Name [1]	Leonhardt's Launchpads NorCal
Address [1]	University of Northern California 1300 Valley House Dr, Suite # 100-27 Rohnert Park, CA 94928 (707) 664-6365
Country [1]	USA

Ethics approval

Ethics application status	Not Yet Approved
Ethics committee name [1]	TBD
Ethics committee address [1]	TBD
Ethics committee country [1]	TBD
Date submitted for ethics approval [1]	TBD
Approval date [1]	TBD

Ethics approval number [1]	

Summary

Brief summary	The main purpose of this study is to assess how safe and how well a series of biolelectric stimulation signals led by a stem cell homing signal combine with micro infusion of a stem cell based composition, applied to the scalp of male participants who have a condition called male pattern baldness is tolerated. The secondary purpose is to assess how effective the combination of bioelectric stimulation and stem cell based composition infusion is and also to assess the way the body absorbs, distributes and gets rid of the HC-15 composition. .
Trial website	
Trial related presentations / publications	NA
Public notes	

Contacts

Principal investigator	
Name	TBD
Address	
Country	TBD
Phone	
Fax	
Email	

Contact person for public queries	
Name	TBD
Address	TBD
Country	TBD
Phone	
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