



Clinical Trial Details (PDF Generation Date :- Sun, 27 Nov 2022 11:37:51 GMT)

CTRI Number	CTRI/2012/04/002614 [Registered on: 27/04/2012] - Trial Registered Retrospectively	
Last Modified On	10/04/2013	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Biological	
Study Design	Randomized, Parallel Group Trial	
Public Title of Study	A comparative study to determine the safety and efficacy of Autologous Human Platelet Lysate (HPL) for Treatment of Androgenetic Alopecia (AGA)	
Scientific Title of Study	A Prospective, Multicentric, Open Label, Randomized, Bio-Interventional, Phase I/II Pilot Study To Evaluate The Safety And Efficacy Of Autologous Human Platelet Lysate (HPL) For Treatment Of Androgenetic Alopecia (AGA)	
Secondary IDs if Any	Secondary ID	Identifier
	KRPL/HPL-AGA/11-12/001A	Other
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
	Name	Dr Rajendarsingh Rajput
	Designation	Hair Restorative Surgeon
	Affiliation	
	Address	Dr. Rajesh Rajput Hair Restore 201 A Wing, Gasper Enclave Pali Market Bandra West Mumbai MAHARASHTRA 400050 India
	Phone	022-26415298
	Fax	
	Email	drrajeshrajput@gmail.com
	Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)
Name		Dr Sandeep Sattur
Designation		Hair Restorative Surgeon
Affiliation		
Address		Hair Revive, 103 Options Commercial Centre Dr Vasant Avasane Marg, Near Milan Subway, Santacruz (West) Mumbai MAHARASHTRA 400054 India
Phone		022-26136575
Fax		
Email		drsattur@yahoo.com
Details Contact Person (Public Query)	Details Contact Person (Public Query)	
	Name	Dr Kaushal Shah
	Designation	Head Clinical Research
	Affiliation	
	Address	Kasiak Research Pvt Ltd 1st Floor Building No.1, Dil Complex, Near Tatwagyan Vidyapeeth, Ghodbunder Road, Thane MAHARASHTRA 400610 India



	Phone	022-41173472		
	Fax			
	Email	kaushal.shah@kasiakresearch.com		
Source of Monetary or Material Support	Source of Monetary or Material Support			
	> NIL			
Primary Sponsor	Primary Sponsor Details			
	Name	Kasiak Research Pvt Ltd		
	Address	KASIAK RESEARCH PRIVATE LIMITED 1st Floor, Building No.1, Dil Complex, Near Tatwagyan Vidyapeeth, Ghodbunder Road, Thane (West) - 400610		
	Type of Sponsor	Other [Biotechnology company]		
Details of Secondary Sponsor	Name	Address		
	NIL	NIL		
Countries of Recruitment	List of Countries			
	India			
Sites of Study	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	Dr Rajendarsingh Rajput	Dr. Rajesh Rajput Hair Restore	201 A Wing Gasper Enclave Pali Market Bandra (West) Mumbai 400050 Mumbai MAHARASHTRA	022-26415298 drrajeshrajput@gmail.com
	Dr Sandeep Sattur	Hair Revive	103 Options Commercial Centre Dr Vasant Avasane Marg, Near Milan Subway, Santacruz (West), Mumbai 400054 Mumbai MAHARASHTRA	022-26136575 drsattur@yahoo.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Clinical Ethics Forum (CEF); Mumbai	Approved	28/12/2011	Yes
	Clinical Ethics Forum; Mumbai	Approved	28/12/2011	Yes
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Patients		Androgenetic Alopecia	
Intervention / Comparator Agent	Type	Name	Details	
	Comparator Agent	Standard Therapy	Topical treatments as directed by the Physician	
	Intervention	Autologous Human Platelet Lysate (HPL)	3 doses of HPL will be injected intradermally at an interval of one month each.	
Inclusion Criteria	Inclusion Criteria			
	Age From	18.00 Year(s)		
	Age To	50.00 Year(s)		



Gender	Male	
Details	1. Male subjects, aged between 18 to 50 years (both inclusive) and in general good health 2. Subjects willing to refrain from other AGA treatments during the entire study duration 3. Subjects who are willing to give informed consent and adhere to the study protocol. 	
Exclusion Criteria	Exclusion Criteria	
Details	1. Subjects aged 50 years 2. Subjects with dermatological disorder of scalp that might interfere with study evaluation 3. Subjects on Anti-coagulant therapy 4. Subjects with clinically significant medical or psychiatric disease as determined by the investigator. 5. Subjects with dermatological disorder of scalp that might interfere with study evaluation 6. Subjects unwilling to or unable to comply with the study protocol.	
Method of Generating Random Sequence	Permuted block randomization, fixed	
Method of Concealment	Centralized	
Blinding/Masking	Open Label	
Primary Outcome	Outcome	Timepoints
	1. Improvement in Calibre & Density of Hair as assessed by Folliscope 2. Photographic assessment from randomization to end of study	End of Study- 6 Months
Secondary Outcome	Outcome	Timepoints
	1. Physician's assessment score 2. Patient's self assessment score	End of Study- 6 Months
Target Sample Size	Total Sample Size=20 Sample Size from India=20 Final Enrollment numbers achieved (Total)= Final Enrollment numbers achieved (India)=	
Phase of Trial	Phase 1/ Phase 2	
Date of First Enrollment (India)	25/01/2012	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	Years=0 Months=9 Days=0	
Recruitment Status of Trial (Global)	Not Applicable	
Recruitment Status of Trial (India)	Completed	
Publication Details		
Brief Summary	This is a multicentre, open label, randomized, pilot study to evaluate safety and efficacy of Human Platelet Lysate (HPL) in subjects with Androgenetic Alopecia. The study is being conducted at 2 centers in India. The primary endpoints are Improvement in Caliber & Density of hair and Improvement in Photographic assessment from randomization to end of study. The secondary endpoints are Physicians and Patients self assessment score.	