Clinical Trial Details (PDF Generation Date :- Fri, 14 Aug 2020 10:29:20 GMT)

CTRI Number	CTRI/2013/01/003283 [Registered on: 02/01/2013] - **Trial Registered Prospectively**
Last Modified On	27/11/2018
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Other (Specify) [Cosmetic]
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	Evaluate effect and safety Of VB-001, an Antidandruff Hair Oil Regime In Comparison With Head & Shoulders® Antidandruff Shampoo (P&G) Regime In Subjects With Moderate Adherent Dandruff Of The Scalp
Scientific Title of Study	Efficacy and in use skin safety Of VB-001, an Antidandruff Hair Oil Regime In Comparison With Head & Shoulders® Antidandruff Shampoo (P&G) Regime In Subjects With Moderate Adherent Dandruff Of The Scalp

Secondary IDs if Any

Secondary ID	Identifier
CL/028/1212/STU	Protocol Number
VYB/CD/001 - Version: 004	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Rajiv Joshi
Designation	Principal Investigator
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
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Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Abhijit Bapat
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Vyome Biosciences Private Limited. Plot No. 459 (1st Floor) & 465 (Ground Floor) F.I.E. Patparganj Industrial Area Delhi 110092 India

Primary Sponsor

Primary Sponsor Details	
Name	Vyome Biosciences Private Limited
Address	Plot No. 459 (1st Floor) & 465 (Ground Floor) F.I.E. Patparganj Industrial Area Delhi 110092 India
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
None	Not Applicable

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Rajiv Joshi	C.L.A.I.M.S Pvt. Ltd.	4th Floor, B Wing, Modi House, C-10, Dalia Industrial Estate, New Link Road, Andheri (W), Mumbai-400058. Mumbai MAHARASHTRA	66758851 66758854 rsjdr@rediffmail.com
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Dr Yatin Jadhav	Springs Skin and Cosmetology Laser Clinic. Pvt. Ltd.	Springs Skin and Cosmetology Laser Clinic. Pvt. Ltd. Jade Garden,Swarvihar Gruha Sankul Khend Chiplun District Ratnagiri 415605	02355261234 02355260677 springscosmetologyclinic@gmail.com

		Maharashtra, India Ratnagiri MAHARASHTRA	

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Independent Ethics Committee, Mumbai	Approved	21/12/2012	Yes
MGM Institute of health Sciences Institutional Ethics Committee	Approved	22/01/2013	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	with a clinical diagnosis of moderate adherent dandruff of the scalp.

Intervention / Comparator Agent

Type	Name	Details
Intervention	Antidandruff hair oil regime	Antidandruff hair oil (active ingredient Piroctone Olamine) application of 10ml of Product daily, overnight (at least for 8 hours leave on) with massage onto the scalp Subjects will wash their head on the next day of IP application with Pantene Pro Lively Clean® shampoo. This procedure will be continued for 2 weeks.
Comparator Agent	Head & Shoulders® Shampoo	Subjects will be instructed to apply the antidandruff Head & Shoulders® Shampoo and Pantene Pro V® Non anti Dandruff Conditioner alternate days for 2 weeks.

Inclusion Criteria

Inclusion Criteria	
Age From	15.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1. Healthy males or females aged ? 15 years and ? 65 with a clinical diagnosis of moderate adherent dandruff of the scalp. 2.Understand and willing to sign written informed consent in case of adults and written parental consent form and child assent form in case of children wherever applicable. 3. Must be willing and able to comply with protocol, including measures of subject compliance. 4. Must have active adherent dandruff of the scalp with a minimum score of 6 and not exceeding 14; baseline scaling scoring of at least 3 and not more than 4 of adherent flaking in at least one zone of the scalp (6 zones- 2 frontal, 2 parietal plus temporal and 2 occipital) . 5. Investigators global assessment (IGA) for pruritis score of at least 1. 6. Should not have used an antidandruff agent in the past 14 days. 7. Willing to refrain from use of all other topical medications that would affect the results of the trial, including medicated shampoos/oils or antibiotics, during the treatment and observation periods (from day 0 to day 14).

Exclusion Criteria

Exclusion Criteria	
Details	1. Pregnant or Lactating Women by history. 2. No history of overt bacterial, viral or fungal infection of the head/neck. 3. No history or presence of compromising dermatosis elsewhere on the skin. 4. No actinically damaged skin 5. Presence of any skin condition that would interfere with the diagnosis or assessment of adherent dandruff; e.g., psoriasis, acne, atopic dermatitis. 6. Clinically significant systemic disease (e.g., immunological deficiencies, AIDS, current malignancies, uncontrolled diabetes mellitus). 7. Use within 1 month prior to baseline of any treatment that would affect the results of the trial, including 1) systemic antifungals, 2) systemic steroids 3) systemic antibiotics 4) systemic anti-inflammatory agents or 5) cytostatic or immunomodulating drugs (e.g., cyclosporine, tacrolimus, pimecrolimus). 8. Use within 2 weeks prior to baseline of any treatment that would affect the results of the trial, including 1) topical steroids 2) topical retinoids 3) topical anti-inflammatory agents 4)topical antibiotics or 5) topical treatment of adherent dandruff (e.g., coal tar preparations, antidandruff shampoos/oils/gels/creams/conditioners 6) antihistamines.

Method of Generating Random Sequence	Other
Method of Concealment	Other
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
To evaluate efficacy of VB-001, antidandruff hair oil regime in comparison with Head & Shoulders® Antidandruff Shampoo (P&G) regime in subjects with Moderate adherent dandruff of the scalp.	0,5 ,9,and 14 days

Secondary Outcome

Outcome	Timepoints
To evaluate in use skin safety VB-001, antidandruff hair oil regime in comparison with Head & Shoulders® Antidandruff Shampoo (P&G) regime in subjects with Moderate adherent dandruff of the scalp	0,5 ,9,and 14 days

Target Sample Size	**Total Sample Size=**168 **Sample Size from India=**168 **Final Enrollment numbers achieved (Total)=**159 **Final Enrollment numbers achieved (India)=**159
Phase of Trial	N/A
Date of First Enrollment (India)	16/01/2013
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**4 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of	Completed

Trial (India)	
Publication Details	
Brief Summary	• Subjects will be screened at visit 1, and if they meet the inclusion/exclusion criteria they will be randomized for inclusion. • At Visit 2, Day 0, subjects will be allocated to any 1 of the 2 groups as per randomization to receive either Antidandruff hair oil (VB-001) or Head & Shoulders® Antidandruff Shampoo (P&G). • Thereafter clinical evaluation of test site will be carried out. • Severity of dandruff and pruritis would be graded using clinical scales. • Photographs of the scalp will be taken at all visits. • Subjective questionnaire will be taken at all visits. • Baseline data will be captured at Visit 2 (Day 0). Follow-up visits to collect similar data and hence evaluate efficacy of test products will be done at Visit 3 (D05), Visit 4 (D09) and Visit 5 (D14). • Product will be dispensed to subjects at Visit 2(D0) and compliance will be checked at all visits. • Subjects will be required to maintain a diary to monitor product compliance. • The Products will be dispensed for application at home. • About 300 volunteers in the age group of 15 – 65 years will be screened to get 168 volunteers (84 in each of 2 groups) for the entire study.