



Clinical Trial Details (PDF Generation Date :- Wed, 07 Jun 2023 16:38:08 GMT)

CTRI Number	CTRI/2020/10/028698 [Registered on: 28/10/2020] - Trial Registered Prospectively	
Last Modified On	15/02/2021	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Nutraceutical	
Study Design	Non-randomized, Multiple Arm Trial	
Public Title of Study	Clinical trial of Nutraceutical product Power Gummies : hair and nail vitamin.	
Scientific Title of Study	A parallel arm clinical trial to evaluate safety and efficacy of Power Gummies : hair and nail vitamin; in hair fall reduction, accelerated hair growth, strengthening of hair with overall hair and scalp health improvement in healthy female and male.	
Secondary IDs if Any	Secondary ID	Identifier
	MHC/CT/20-21/004 Version 1.0 dated, 21st July 2020	Protocol Number
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
	Name	Dr Umesh Gajare
	Designation	Consultant
	Affiliation	Jyoti Clinic and Research Centre
	Address	OPD 1, Ground floor, B-3 Saipritam , kaliwadi- Rahatni link Road, Kalewadi, Pune-17 Pune MAHARASHTRA 411017 India Pune MAHARASHTRA 411017 India
	Phone	8796739140
	Fax	
	Email	dr.gajareumesh@gmail.com
Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Dr Gayatri Ganu
	Designation	Managing Director
	Affiliation	Mprex Healthcare Pvt. Ltd.
	Address	501, Crossroads, Wakad, Pune Pune MAHARASHTRA 411057 India Pune MAHARASHTRA 411057 India
	Phone	8554912644
	Fax	
	Email	gayatri.mbgindia@gmail.com
Details Contact Person (Public Query)	Details Contact Person (Public Query)	
	Name	Mr Kapil Mittal
	Designation	Chief Strategic Officer
	Affiliation	Aesthetic Nutrition Pvt. Ltd.
	Address	M 31 , M Block Market, Greater Kailash 2, New Delhi South DELHI 1100048 India
	Phone	9910666670



	Fax			
	Email	cso@powergummies.com		
Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Aesthetic Nutrition Pvt. Ltd.			
Primary Sponsor	Primary Sponsor Details			
	Name	Aesthetic Nutrition Pvt Ltd		
	Address	M 31 , M Block Market, Greater Kailash 2, New Delhi- 1100048		
	Type of Sponsor	Pharmaceutical industry-Indian		
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 Sarita Tippannawar	Renaissance Derma Clinic	Office No. 504, Crossroads, Opposite Hotel Ginger, Bhumkar Chowk, Wakad Pune-411057 Pune MAHARASHTRA Pune MAHARASHTRA	9370665436 saritatippannawar17@gmail.com
	Dr Umesh Gajare	Skinovate Laser & Cosmetic Surgery Center LLP	Office Number 302 & 303, 3rd Floor, Royal Avenue Landmark: Next to Hotel Shivar Garden, Pimple Saudagar, Pune Pune MAHARASHTRA Pune MAHARASHTRA	9422420986 dr.gajareumesh@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Lokmanya Medical Research Centre	Approved	20/09/2020	No
	Royal Pune Independent Ethics Committee	Approved	09/10/2020	Yes
Regulatory Clearance Status from DCGI	Status	Date		
	Not Applicable	No Date Specified		
Health Condition / Problems Studied	Health Type	Condition		
	Healthy Human Volunteers	Scalp, hair and nail health.		
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	Power Gummies: Hair and Nail Vitamin	1 Power Gummy per day for 90 days after each meal.	
	Comparator Agent	NA	NA	
Inclusion Criteria	Inclusion Criteria			
	Age From	18.00 Year(s)		
	Age To	40.00 Year(s)		
	Gender	Both		



Details	Male and Female subjects in general good health, subjects in the age group 18-40 years, subjects willing to to give written informed consent and agree to come for a regular follow up visit, subjects not participated in a similar investigations in the past two weeks, subjects complaining of hair fall and damage, subjects who are not on crash dieting, subjects who agree to not to change the brand of currently used hair color, dye, treatment etc., if during the study term, subjects willing to refrain from any type of hair treatment like head massage, oil application, perming, etc. during the study duration, subjects with at least of two of following complaints- dry damaged hair, brittle and thin hair, premature greying of hair, scalp related complaints like itching, dandruff or irritation	
Exclusion Criteria	Exclusion Criteria	
Details	Subjects who are undergoing hair growth treatment within 3 months before screening into the study. Subjects having any active scalp disease which may interfere in the study. Subjects on treatment for active acne Subjects with history or active phase of malignancy and chemotherapy therefore. Subjects who have history of alcoholism and/ or psychiatric disorder including trichotillomania. Subjects who have had hair transplant. Subjects who take pharmaceutical product which cause hirsutism. Subjects on oral hair growth medications which will compromise the study. Subjects who are pregnant lactating or nursing as established with medical history. Chronic illness which may influence the study. Subjects participating in other similar cosmetic or therapeutic trial within last two weeks Any history of underlying uncontrolled medical illness including diabetes mellitus, hypertension, HIV, hepatitis, severe anemia, serious disorder of heart and respiratory apparatus or any other serious medical illness	
Method of Generating Random Sequence	Not Applicable	
Method of Concealment	Not Applicable	
Blinding/Masking	Not Applicable	
Primary Outcome	Outcome	Timepoints
	Change in the number of terminal hairs and vellus hairs in the target area of the scalp from baseline to end of study identified by Phototrichograms. Reduction change in the shedding range of the hair in the "60 Second Hair Comb test" from baseline to end of the study. (Hair strength) Change in follisopic measurement of hair density and hair diameter (Hair Density), Change in nail growth and satisfaction scale on nail health	Baseline, day 30, day 60 and day 90
Secondary Outcome	Outcome	Timepoints
	Improvement in the Hair Assessment Questionnaire, Improvement in the Modified hair wash test (Brittleness and hair loss after	Baseline, day 30, day 60 and day 90



washing), Improvement in quality of hair, VAS- Visual analog scale scalp related complaints like itching, dandruff or irritation (Scalp health), Premature graying, Assessment of tolerability of study drug by assessing adverse events, serious adverse events during the study period, Assessment of Global evaluation of overall improvement in scalp and hair.

Target Sample Size	Total Sample Size=60 Sample Size from India=60 Final Enrollment numbers achieved (Total)=60 Final Enrollment numbers achieved (India)=60
Phase of Trial	Phase 1/ Phase 2
Date of First Enrollment (India)	31/10/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	Years=0 Months=6 Days=0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	NIL
Brief Summary	<p>The results of this study showed that the administration of Power Gummies: hair and nail vitamin was safe and effective in hair fall reduction, accelerated hair growth, strengthening of hair with overall hair and scalp health improvement in healthy females and males in 90 days.</p> <p>The results showed a significant increase in the hair density, number of the terminal, vellus hair counts at 90 days in a gradual way.</p> <p>There was an increase in terminal hair count from baseline to day 90. There was an increase in vellus hair count, it is possible that vellus hair get converted in terminal hair to improve the hair density.</p> <p>The beneficial effects of Power Gummies were observed in both male and female hence it's an efficacious product for both genders.</p> <p>Power Gummies presented excellent compliance and tolerability with no adverse events related to its long term consumption.</p> <p>These measurements were accompanied by significant and progressive visible clinical improvement in hair growth and hair quality for the treatment group, as determined by the investigator.</p> <p>These outcomes demonstrated a steady improvement from baseline to</p>



day 90, suggesting that improvement may progress with continued treatment. There was also a strong trend in reducing hair breakage and improving hair density as well as hair diameter hence making hairs stronger and may improve hair length as well.

The hair with the consumption of Power Gummies was less brittle and strong from roots that there was decreased hair fall in the hair comb and wash test. It is suggestive of the improved strength of the hair.

There was satisfactory around 10% in female and 5% in male the enhanced growth rate of nails.

It was observed from the study that there was improved satisfaction through augmented stronger and longer nails in subjects.