



Clinical Trial Details (PDF Generation Date :- Sun, 13 Jun 2021 01:29:51 GMT)

CTRI Number	CTRI/2012/03/002522 [Registered on: 27/03/2012] - Trial Registered Retrospectively	
Last Modified On	27/03/2012	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Nutraceutical	
Study Design	Randomized, Parallel Group, Placebo Controlled Trial	
Public Title of Study	A clinical trial to study the effects of drugs Calmagen cream and lotion in patients for topical treatment of Tinea (ringworm infection).	
Scientific Title of Study	A single centre, double blind, placebo controlled, randomized, confirmatory efficacy study of biovite@s calmagenTM dermatological cream & lotion for the topical treatment of tinea	
Secondary IDs if Any	Secondary ID	Identifier
	MA-CT-09-012	Protocol Number
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
	Name	Dr Manoj Parekh
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Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
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Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Biovite Australia Pty Ltd			
Primary Sponsor	Primary Sponsor Details			
	Name	Biovite Australia Pty Ltd		
	Address	(Biovite)Unit 1, Enterprise Plaza45 Township DriveWest Burleigh, Queensland 4219 AUSTRALIA		
	Type of Sponsor	Research institution		
Details of Secondary Sponsor	Name	Address		
	NIL			
Countries of Recruitment	List of Countries			
	India			
Sites of Study	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	Dr Manoj Parekh	The Apollo Clinic	#65, Madhavaraya Mudliar Road,-560005 Bangalore KARNATAKA	080-25808081 drmanojparekh@yahoo.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Clinicom, Bangalore	Approved	22/01/2010	Yes
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Patients		Superficial Tinea Infections	
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	Biovites® Calmagen™ Dermaceutical cream & lotion,	Twice daily, Topical application for 4 weeks	
	Comparator Agent	A matching placebo cream & lotion,	Twice daily Topical application for 3 months; once daily for 3 months (during observation phase)	
Inclusion Criteria	Inclusion Criteria			
	Age From	18.00 Year(s)		
	Age To	99.00 Year(s)		
	Gender	Both		
	Details	To be eligible for entry in this study, patient must: 1. Be a male or female ? 18 years of age 2. Be diagnosed by the Principal Investigator or designee as suffering from Tinea of combined severity (itching, erythema and scaling) score of 8 or more as in appendix 3 or severe grade of onychomycosis as in appendix 4 of protocol 3. Subjects with positive KOH and positive fungal culture test along with identification of the dermatophyte and presence of live spores. 4. Understand and conform to the procedures involved in and agree to participate in the study by giving informed, written consent. 5. Be able to give consent for taking photographs of the affected region before, during and after the study period. 		
Exclusion Criteria	Exclusion Criteria			
	Details	To be eligible for entry in this study, patient must not:		



	<ol style="list-style-type: none"> 1. Have used any oral or topical Tinea treatments, within one week prior to the screening assessment. 2. Have ingested any drug in the week prior to the start of treatment or during the treatment period, which, in the opinion of the Principal Investigator, could compromise the study (Note: Oral, injectable or implant contraceptive for female volunteers is acceptable). 3. Have history of allergy or intolerance to any drug, which in the opinion of the principal investigator poses a risk to the patient 4. Be pregnant or breast-feeding females. 5. Have received an investigational drug or participated in a clinical trial within the last 30 days 6. Have clinically serious and/or unstable intercurrent infection, medical illnesses or conditions that are uncontrolled or whose control, in the opinion of the Principal Investigator, may be jeopardized by participation in this study or by the complications of this therapy 7. Hypersensitivity to Biovite® dermaceutical formulation (cream & lotion) 8. Patient with a positive test for hepatitis B, C, and who is positive or reactive for antibodies to HIV 1 and 2.
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Method of Generating Random Sequence	Stratified block randomization	
Method of Concealment	Centralized	
Blinding/Masking	Participant and Investigator Blinded	
Primary Outcome	Outcome	Timepoints
	Mycological cure assessed by negative KOH preparation, fungal culture, and reduction in live spore counts at the end of study	End of study (4 weeks for Tinea & 12 weeks for Onychomycosis)
Secondary Outcome	Outcome	Timepoints
	Reduction in the extent and the severity of onychomycosis since baseline and at the end of the study.	End of study (12 weeks for Onychomycosis)
	Reduction in the size and the severity of tinea lesions since baseline and at the end of study	End of study (4 weeks for Tinea)
	Improvement in lesions assessed by photographic record at baseline and at end of study	End of study (4 weeks for Tinea and 12 weeks for Onychomycosis)
Target Sample Size	Total Sample Size=28 Sample Size from India=28 Final Enrollment numbers achieved (Total)= Final Enrollment numbers achieved (India)=	
Phase of Trial	Phase 2	
Date of First Enrollment (India)	27/03/2010	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	Years=0 Months=10	



	Days=0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	NIL
Brief Summary	<p>This is a randomized, double blind, placebo controlled, parallel-group, single center, study designed to confirm the efficacy of Biovite®'s Calmagen™ Dermaceutical cream & lotion for topical application to the affected areas of skin in patients of either sex with severe to very severe presentations of Tinea. The study is divided in three main phases: (a) 1 to 15- days Screening Phase and Randomization (b) Variable Treatment Phase (2 to 12 weeks) (c) Observation phase (12 weeks) The study population will consist of ambulatory human adult male and female patients with clinically proven severe presentations of Tinea who will be randomized to receive either: Treatment A: Biovite®'s Calmagen™ Dermaceutical cream or lotion for topical application to the affected areas of skin or nails. Treatment B: Placebo cream or lotion for topical application to the affected areas of skin or nails.</p> <p>The constituents of Biovites Calmagen dermaceutical cream are: very early form of plant life ("Bioactive") named AMYCOT</p>