Clinical Trial Details (PDF Generation Date :- Tue, 15 Oct 2019 06:30:15 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 dermaceutical 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)

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Details Contact Person (Public 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® CalmagenTM 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: 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.

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	This is a randomized, double blind, placebo controlled, parallel-group, single center, study designed to confirm the efficacy of Biovite®'s CalmagenTM 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 CalmagenTM 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. The constituents of Biovites Calmagen dermaceutical cream are: very early form of plant life ("Bioactive") named AMYCOT