



Pharmacokinetics and Tolerability of Topically Applied Benvitimod Cream in Patients with Psoriasis

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Registration number:	ChiCTR-TRC-10000995		
Date of Last Refreshed on:	2016-10-07		
Date of Registration:	2010-09-03		
Registration Status:	Retrospective registration		
Public title:	Pharmacokinetics and Tolerability of Topically Applied Benvitimod Cream in Patients with Psoriasis		
English Acronym:			
Scientific title:	Pharmacokinetics and Tolerability of Topically Applied Benvitimod Cream in Patients with Psoriasis		
The registration number of the Partner Registry or other register:			
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Applicant address: 11 Xizhimen South Street, Beijing, China	Study leader's address: 11 Xizhimen South Street, Beijing, China										
Applicant postcode: 100044	Study leader's postcode: 100044										
Applicant's institution: Department of Dermatology, People's hospital, Peking University											
Affiliation of the Leader:											
Approved by ethic committee: Yes											
Approved No. of ethic committee: [2010]10	Approved file of Ethical Committee:										
Name of the ethic committee: The ethics committee of People's Hospital, Peking University											
Date of approved by ethic committee: 2010-03-09											
Contact Name of the ethic committee:											
Contact Address of the ethic committee:											
Contact phone of the ethic committee:	Contact email of the ethic committee:										
Primary sponsor: People's hospital, Peking University											
Primary sponsor's address: 11 Xizhimen South Street, Beijing, China											
Secondary sponsor:	<table border="1"> <tr> <td>Country:</td> <td>China</td> <td>Province:</td> <td>Guangdong</td> <td>City:</td> </tr> <tr> <td>Institution hospital:</td> <td>Celestial Pharmaceutical(Shenzhen) co.,Ltd.</td> <td>Address:</td> <td colspan="2">Room 502A, Wuzi building, 3092 Renminbei Road, Luohu District, Shenzhen, Guangdong, China</td> </tr> </table>	Country:	China	Province:	Guangdong	City:	Institution hospital:	Celestial Pharmaceutical(Shenzhen) co.,Ltd.	Address:	Room 502A, Wuzi building, 3092 Renminbei Road, Luohu District, Shenzhen, Guangdong, China	
Country:	China	Province:	Guangdong	City:							
Institution hospital:	Celestial Pharmaceutical(Shenzhen) co.,Ltd.	Address:	Room 502A, Wuzi building, 3092 Renminbei Road, Luohu District, Shenzhen, Guangdong, China								
Source(s) of funding:	Celestial Pharmaceutical(Shenzhen) co.,Ltd.										
Target disease:	Plaque Psoriasis										
Target disease code:											
Study type:	Interventional study										
Study phase:	1-2										

Study design:	Parallel		
Objectives of Study:	Primary: 1. To evaluate the safety and tolerability of topically applied Benvitimod cream; 2. To assess the pharmacokinetics of topically applied Benvitimod cream based on plasma concentrations. Secondary: To obtain an initial evaluation of the efficacy of topically applied Benvitimod cream.		
Description for medicine or protocol of treatment in detail:			
Inclusion criteria:	Healthy male and female patients with Psoriasis aged 18 to 65 years, inclusive 1. In good general health and free of any disease state or physical condition that might impair evaluation of plaque psoriasis; 2. A clinical diagnosis of stable plaque psoriasis for >6 months representing a maximum of 10% of BSA and a minimum of 2% BSA of their total body surface area (excluding the face, groin, scalp, and genital regions); 3. Willing and able to comply with the protocol and attend all study visits; 4. Provide written informed consent prior to the initiation of any study-related procedures.		
Exclusion criteria:	1. Other concomitant serious illness or medical condition (e.g., human immunodeficiency virus, renal insufficiency, clinically significant abnormal laboratory values) that could put a patient at risk during the study; 2. History of neurological/psychiatric disorders, including psychotic disorders or dementia, or any other reason that would interfere with the patient's participation in the trial; 3. Pregnancy or lactation; 4. Known or suspected hypersensitivity to any of the constituents of the investigational product; 5. Treatment with other investigational drug within 3 months of day 0 or current participation in another clinical trial; 6. Spontaneously improving or rapidly deteriorating plaque psoriasis; 7. Any other skin diseases that might interfere with the clinical assessment of plaque psoriasis and/or put the patient at risk; 8. Pustular, erythrodermic, or other non-plaque forms of psoriasis; 9. Guttate psoriasis as the dominant form of psoriasis; 10. Use of any psoriasis vaccine or previous participation in an investigational study of any psoriasis vaccine; 11. Systemic immunomodulatory therapy known to affect psoriasis and decreases immune cell populations (e.g., alefacept) within 36 weeks prior to the baseline visit; 12. Systemic immunomodulatory therapy known to affect psoriasis and that does not typically decrease immune cell populations (e.g., etanercept) within 12 weeks prior to the baseline visit; 13. Any phototherapy (including laser), photo-chemotherapy, or systemic psoriasis therapy (such as systemic corticosteroids, methotrexate, retinoids, or cyclosporine) within 4 weeks prior to the baseline visit; 14. Prolonged exposure to natural or artificial sources of ultraviolet (UV) radiation within 4 weeks prior to the baseline visit or intention to have such exposure during the study, thought by the investigator likely to modify the patient's psoriasis; 15. Topical anti-psoriatic therapy (including topical retinoids and vitamin D analogs) on the areas to be treated within 2 weeks prior to the baseline visit; 16. Alcohol abuse in the last 2 years as defined by consumption of >14 standard drinks of alcohol per week; 17. Use of lithium within 2 weeks prior to the screening visit; 18. Use of beta-blockers (e.g., propranolol) within 2 weeks prior to the screening visit unless on a stable dose for >3 months.		
Study execute time:	From 2010-05-01 To 2010-09-30		Recruiting time: From 2010-04-01 To 2010-07-31
Interventions:			
	Group:	1	Sample size: 12

Intervention:	0.5% Benvitimod cream	Intervention code:	
Group:	2	Sample size:	12
Intervention:	1.0% Benvitimod cream	Intervention code:	
Group:	3	Sample size:	12
Intervention:	1.5% Benvitimod cream	Intervention code:	
Countries of recruitment and research settings:	Country: China	Province: Beijing	City:
	Institution hospital: Department of Dermatology, People's hospital, Peking University	Level of the institution: Tertiary A hospital	
Outcomes:	Outcome: Adverse Events	Type: Primary indicator	
	Measure time point of outcome:	Measure method:	
	Outcome: PASI	Type: Primary indicator	
	Measure time point of outcome:	Measure method:	
	Outcome: Hematology	Type: Primary indicator	
	Measure time point of outcome:	Measure method:	
	Outcome: Clinical Chemistry	Type: Primary indicator	
	Measure time point of outcome:	Measure method:	
	Outcome: PGA	Type: Primary indicator	

Measure time
point of outcome:

Measure method:

Outcome: Photographs of Target Plaques

Type: Primary indicator

Measure time
point of outcome:

Measure method:

Outcome: Urine routine test

Type: Primary indicator

Measure time
point of outcome:

Measure method:

Outcome: Vital Signs

Type: Primary indicator

Measure time
point of outcome:

Measure method:

Outcome: ECGs

Type: Primary indicator

Measure time
point of outcome:

Measure method:

Collecting sample(s)
from participants:

Recruiting status: /Completed

Participant age: Min age 18 years
Max age 65 years

Gender: Both

Randomization Procedure (please state who generates the random number sequence and by what method):
computer software

Calculated Results after the Study Completed public access:

Blinding: Celestial Pharmaceutical(Shenzhen) co., Ltd.: Blinding

Calculated Results after download

the Study Completed(upload file):

IPD sharing **No**

The way of sharing IPD"(include met
adata and protocol, If use web-based
public database, please provide the u
ri):
elestial Pharmaceutical(Shenzhen) co.,Ltd.

Data collection and Management (A s
tandard data collection and manage
ment system include a CRF and an e
lectronic data capture:
Beijing Bozhiying s&t co.,Ltd

Data and Safety Monitoring Committ
ee:

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[ICP 16010396-9-9](#)

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