



Trial search

Nation,
Province(City)Code of
diseasePrimary
sponsor(s)Secondary
sponsor(s)Funding
sourceRecruiting
statusRegister
status

Measure

Ethical
committee

Study type

Multi-centre, randomised, double-blind, placebo- and comparator-controlled trial on topically applied benvitimod cream in patients with psoriasis

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Registration number: ChiCTR-TRC-13003259

Date of Last Refreshed on: 2016-02-08

Date of Registration: 2013-04-07

Registration Status: Prospective registration

Public title: Multi-centre, randomised, double-blind, placebo- and comparator-controlled trial on topically applied benvitimod cream in patients with psoriasis

English Acronym:

Scientific title: Multi-centre, randomised, double-blind, placebo- and comparator-controlled trial on topically applied benvitimod cream in patients with psoriasis

The registration number of the Partner Registry or other register:

Applicant: Genhui Chen

Study leader: Zhang jian-zhong

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Applicant Fax:

Study leader's fax:

Applicant E-mail: genhui@sfu.ca

Study leader's E-mail: rmzjz@126.com

Applicant website(voluntary supply):		Study leader's website(voluntary supply):				
Applicant address:	Room1628, Block B Lucky Tower, 3 North Dongsanhuan Road, Chaoyang District, Beijing, China	Study leader's address:	11 South Xizhimen Street, Beijing, China			
Applicant postcode:	100027	Study leader's postcode:	100044			
Applicant's institution:	Beijing Wenfeng Tianji Pharmaceutical Technology					
Affiliation of the Leader:						
Approved by ethic committee:	Yes					
Approved No. of ethic committee:	[2012]院伦审药临字第 (07) 号	Approved file of Ethical Committee:				
Name of the ethic committee:	Ethics Committee of People's Hospital of Peking University					
Date of approved by ethic committee:	2012-11-07					
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 of Peking University					
Primary sponsor's address:	11 South Xizhimen Street, Xicheng District, Beijing, China					
Secondary sponsor:	Country:	China	Province:	Guangdong	City:	Shenzhen
	Institution hospital:	Celestial Pharmaceutical (Shenzhen) co.,Ltd.	Address:	Nanshan District, Shenzhen,China		
	Country:	China	Province:	Beijing	City:	
	Institution hospital:	Beijing Wenfeng Tianji Pharmaceutical Co., Ltd.	Address:	29 Shengming Road, Huilongguan Town Changping District, Beijing, China		
Source(s) of funding:		Beijing Wenfeng Tianji Pharmaceutical Technology Co., Ltd.				

Target disease:	Plaque psoriasis
Target disease code:	
Study type:	Interventional study
Study phase:	3
Study design:	Parallel
Objectives of Study:	To evaluate the efficacy and the safety of topically applied benvitimod cream in patients with psoriasis.
Description for medicine or protocol of treatment in detail:	
Inclusion criteria	1. Male and female patients with plaque psoriasis aged 18 to 65 years; 2. A clinical diagnosis of stable plaque psoriasis representing a maximum of 10% of their total body surface area (excluding the face, groin, scalp, and genital regions); 3. Have a baseline PGA of ≥ 2; 4. Have a minimum of one plaque that is at least 2*2cm in size; 5. In good general health and free of any disease state or physical condition that might impair evaluation of plaque psoriasis; 6. WOCBP using and willing to continue to use adequate contraceptive precautions for the duration of the study; 7. Willing and able to comply with the protocol and attend all study visits, 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. ALT or AST representing liver function is two times larger than the upper limit of normal value, or serum creatinine representing renal function, is higher than the upper limit of normal value; 3. The current diagnosis of non-plaque form psoriasis (such as erythema, guttate and joint psoriasis), and progression of psoriasis vulgaris, drug-induced psoriasis vulgaris; skin lesions reach more than 10% of total body surface; 4. Palmoplantar psoriasis; 5. Pregnancy, lactation or who plan to be pregnant; 6. Known or suspected hypersensitivity to any of the constituents of the investigational product; 7. Treatment with other investigational drug within three months of day 0 or current participation in another clinical trial; 8. Alcohol dependent patients; 9. The frequent use of herb, sedatives, hypnotics, stabilizer and other addictive drugs; 10. Any other skin diseases that might interfere with the clinical assessment of plaque psoriasis and/or put the patient at risk; 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. Any phototherapy (including laser), photo-chemotherapy, or systemic psoriasis therapy (such as systemic corticosteroids, methotrexate, retinoids, or cyclosporine) within four weeks prior to the baseline visit; 13. Topical anti-psoriatic therapy (including topical retinoids and vitamin D analogs) on the areas to be treated within two weeks prior to the baseline visit; 14. The subjects may not the study because of other reasons, or whose researchers think are unsuitable for this study;
Study execute time:	From 2013-03-01 To 2014-12-31
Recruiting time:	From 2013-04-20 To 2014-12-31

Interventions:	Group:	A	Sample size:	360	
	Intervention:	1.0% Benvitimod cream	Intervention code:		
	Group:	B	Sample size:	180	
	Intervention:	Placebo	Intervention code:		
	Group:	C	Sample size:	180	
	Intervention:	Calcipotriene Ointment	Intervention code:		
Countries of recruitment and research settings:	Country:	China	Province:	Beijing	City:
	Institution hospital:	People's Hospital Peking University	Level of the institution:	Tertiary	
	Country:	China	Province:	Beijing	City:
	Institution hospital:	Peking Union Medical College Hospital	Level of the institution:	Tertiary	
	Country:	China	Province:	Beijing	City:
	Institution hospital:	The first people's Hospital of Peking University	Level of the institution:	Tertiary	
	Country:	China	Province:	Shanghai	City:
	Institution hospital:	Huashan Hospital	Level of the institution:	Tertiary	
	Country:	China	Province:	Shanghai	City:
	Institution hospital:	Ruijing Hospital	Level of the institution:	Tertiary	
	Country:	China	Province:	Guangdong	City:
	Institution	Sun yat-sen memorial Hospital	Level of the institution:	Tertiary	

hospital:	n yat-sen University	institution:	
Country:	China	Province:	Tianjin
Institution hospital:	Tianjin Medical University General Hospital	Level of the institution:	Tertiary
Country:	China	Province:	Shanxi
Institution hospital:	Xijing Hospital	Level of the institution:	Tertiary
Country:	China	Province:	Shanxi
Institution hospital:	Second affiliated hospital of Xian Jiaotong University	Level of the institution:	Tertiary
Country:	China	Province:	Zhejiang
Institution hospital:	Zhejiang university medical school affiliated first Hospital	Level of the institution:	Tertiary
Country:	China	Province:	Zhejiang
Institution hospital:	Zhejiang university medical school affiliated second hospital	Level of the institution:	Tertiary
Country:	China	Province:	Chongqing
Institution hospital:	Southwest Hospital	Level of the institution:	Tertiary
Country:	China	Province:	Sichuan
Institution hospital:	Sichuan Provincial People's Hospital	Level of the institution:	Tertiary
Country:	China	Province:	Hunan
Institution hospital:	Xiangya Hospital Central-south	Level of the institution:	Tertiary
Country:	China	Province:	Henan
Institution hospital:	The First Affiliated Hospital of Zhengzhou University	Level of the institution:	Tertiary
Country:	China	Province:	Shandong

Institution hospital:	Shandong Provincial Hospital of Dermatology	Level of the institution:	Tertiary	
Country:	China	Province:	Anhui	City:
Institution hospital:	The First Affiliated Hospital of Medical University Of Anhui	Level of the institution:	Tertiary	
Country:	China	Province:	Jiangshu	City:
Institution hospital:	Skin disease hospital Chinese Academy of Medical Sciences	Level of the institution:	Tertiary	
Country:	China	Province:	Liaoning	City:
Institution hospital:	The First Affiliated Hospital of China Medical University	Level of the institution:	Tertiary	
Country:	China	Province:	Hubei	City:
Institution hospital:	Wuhan Union Hospital	Level of the institution:	Tertiary	
Country:	China	Province:	Yunnan	City:
Institution hospital:	The Second Affiliated Hospital of Kunming Medical University	Level of the institution:	Tertiary	
Country:	China	Province:	Jilin	City:
Institution hospital:	The second hospital of Jilin University	Level of the institution:	Tertiary	
Country:	China	Province:	Heilongjiang	City:
Institution hospital:	The Second Affiliated Hospital of Harbin Medical University	Level of the institution:	Tertiary	

Outcomes:	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:	

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Outcome: PASI

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 generation

Calculated Results after the Study Completed public access:

Blinding: double-blind

Calculated Results after the Study Completed(upload file): download

IPD sharing

The way of sharing IPD"(include metadata and protocol, If use web-based public database, please provide the url): Beijing Wenfeng Tianji Pharmaceutical Technology Co., Ltd.

Data collection and Management (As standard data collection and management system include a CRF and an electronic data capture): FOUNTAIN MEDICAL DEVELOPMENT LTD

Data and Safety Monitoring Committee:

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[Sichuan Huyida Technology Co. LTD](#)

[ICP 16010396-9-9](#)

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