



Trial search

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

Measure

Ethical
committee

Study type

Multicentre, randomised, double-blind, placebo controlled trial on topically applied benvitimod cream in patients with psoriasis

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Registration number: ChiCTR-TRC-11001391

Date of Last Refreshed on: 2015-07-12

Date of Registration: 2011-06-20

Registration Status: Retrospective registration

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

English Acronym:

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

The registration number of the Partner Registry or other register:

Applicant: Zhang jian-zhong

Study leader: Zhang jian-zhong

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Applicant E-mail: rmzjz@126.com

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

Applicant website(voluntary supply):	Study leader's website(voluntary supply):
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: People's Hospital of Peking University	
Affiliation of the Leader:	
Approved by ethic committee: Yes	
Approved No. of ethic committee: [2010]院伦审药临字第 (65) 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: 2010-12-14	
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 Xizhimen South Street,Beijing, China	
Secondary sponsor:	Country: Province: City:
Institution hospital: Celestial Pharmaceutical(Shenzhen) co.,Ltd	Address: Room 502A, Wuzi building, No.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:	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:	Benvitimod														
Inclusion criteria	1. Male and female patients with Plaque Psoriasis aged 18 to 65 years, inclusive; 2. In good general health and free of any disease state or physical condition that might impair evaluation of plaque psoriasis; 3. 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); 4. Have a minimum of 1 plaque that is at least 2*2cm in size; 5. WOCBP using and willing to continue to use adequate contraceptive precautions for the duration of the study; 6. Willing and able to comply with the protocol and attend all study visits; 7. 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 within 36 weeks prior to the baseline visit; 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 4 weeks prior to the baseline visit; 13. Prolonged exposure to natural or artificial sources of ultraviolet (UV) radiation within 4 weeks prior to the baseline visit; 14. 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; 15. Alcohol abuse.														
Study execute time:	From 2011-02-01 To 2011-07-31	Recruiting time:	From 2011-02-01 To 2011-05-31												
Interventions:	<table border="1"> <tr> <td>Group:</td> <td>Group A</td> <td>Sample size:</td> <td>120</td> </tr> <tr> <td>Intervention:</td> <td colspan="3">0.5% Benvitimod cream</td> </tr> <tr> <td></td> <td colspan="3">Intervention code:</td> </tr> </table>			Group:	Group A	Sample size:	120	Intervention:	0.5% Benvitimod cream				Intervention code:		
Group:	Group A	Sample size:	120												
Intervention:	0.5% Benvitimod cream														
	Intervention code:														

Group:	Group B	Sample size:	120
Intervention:	1.0% Benvitimod cream	Intervention code:	
Group:	Group C	Sample size:	120
Intervention:	1.0% Benvitimod cream	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 A hospital	
Country:	China	Province:	Beijing	City:
Institution hospital:	Peking Union Medical College Hospital	Level of the institution:	Tertiary A hospital	
Country:	China	Province:	Shanghai	City:
Institution hospital:	Huashan Hospital	Level of the institution:	Tertiary A hospital	
Country:	China	Province:	Shanghai	City:
Institution hospital:	Ruijing Hospital	Level of the institution:	Tertiary A hospital	
Country:	China	Province:	Guangdong	City:
Institution hospital:	Affiliated hospital of sun yat-sen university third	Level of the institution:	Tertiary A hospital	
Country:	China	Province:	Tianjin	City:
Institution hospital:	Tianjin Medical University General Hospital	Level of the institution:	Tertiary A hospital	
Country:	China	Province:	Shanxi	City:
Institution hospital:	Xijing Hospital	Level of the institution:	Tertiary A hospital	
Country:	China	Province:	Zhejiang	City:

Institution hospital:	Zhejiang university medical school affiliated second hospital	Level of the institution:	Tertiary A hospital
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Country:	China	Province:	Chongqing	City:
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Institution hospital:	Southwest Hospital	Level of the institution:	Tertiary A hospital
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Country:	China	Province:	Liaoning	City:
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Institution hospital:	First Affiliated Hospital of Dalian Medical University	Level of the institution:	Tertiary A hospital
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Country:	China	Province:	Hunan	City:
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Institution hospital:	Xiangya Hospital Central-south	Level of the institution:	Tertiary A hospital
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Outcomes:	Outcome:	PGA	Type:	Primary indicator
	Measure time point of outcome:		Measure method:	
	Outcome:	Photographs of Target Plaque	Type:	Secondary indicator
	Measure time point of outcome:		Measure method:	
	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)

er sequence and by what method):

Calculated Results after the Study Completed public access:

Blinding: CRA: Yes patients: Yes Trialist: Yes

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

Data collection and Management (A standard data collection and management system include a CRF and an electronic data capture: Tigermed Consulting Co., Ltd.

Data and Safety Monitoring Committee:

[return list](#)



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[Sichuan Huyida Technology Co. LTD](#)

[ICP 16010396-9-9](#)

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