



Trial search

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

Measure

Ethical
committee

Study type

Clinical research on Post-marketing Jinlida granule Assessment

Registration number : ChiCTR-TRC-13003159

Date of releasing the registration
number : 2013/04/20

Registration Status : Prospective registration

Public title : Clinical research on Post-marketing Jinlida granule Assessment

Scientific title : The combined Jinlida granule and metformin treatment in patients with type 2 diabetes mellitus:A randomized, parallel-group, multicenter, double-blind and prospective study

Secondary ID :

Applicant : Lian Fengmei

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Applicant website(voluntary
supply) : <http://www.gamhospital.ac.cn/>Study leader's website(voluntary
supply) :

Applicant address : No. 5, Bei Xian Ge, Xuan Wu District, Beijing

Study leader's address : No. 5, Bei Xian Ge, Xuan Wu District, Beijing

Applicant postcode : 100053

Study leader's postcode :

Applicant's institution : Guang'anmen Hospital, China Academy of Chinese medical sciences

Approved by ethic committee : Yes

Approved No. of ethic committee : 2013EC041

Approved file of Ethical Committee :

Name of the ethic committee : Guang'anmen Hospital of China Academy of traditional Chinese medicine ethics committee

Date of approved by ethic
committee : 2013/04/01

Primary sponsor : Guang'anmen Hospital, China Academy of Chinese medical sciences

Primary sponsor's address : No. 5, Bei Xian Ge, Xuan Wu District, Beijing

Secondary sponsor : No data added.

Source(s) of funding : Shijiazhuang YiLing pharmaceutical co., LTD

Target disease : Diabetes Mellitus

Target disease code :

Study type : Interventional

Study phase : Post-market

Objectives of Study : To evaluate the effects of Jinlida particles with Metformin on Glycated hemoglobin, blood sugar, insulin function, body mass index, waist circumference and the role of clinical symptoms in patients who are type 2 diabetes. Glycated hemoglobin as a main observing target, and to evaluate the safety of combined application, to provide clinical evidence for the combined treatment of traditional Chinese medicine and western medicine of diabetes.

Study design : Randomized parallel control

Inclusion criteria : 1.According to WHO diagnostic criteria of type 2 diabetes; 2. Into the group through the specification of diet control +exercise therapy + Stable doses of metformin for more than 3 months; 3.On an empty stomach blood sugar 7.0-13.9mmol/L, or after having meal two hours ≥ 11.1 mmol/L; 4. Glycated hemoglobin $\geq 7.0\%$; 5.18<BMI<40 kg/m²; 6.Ages ranged from 4 to 14 years old; 7.They signed the consent form.

1.Type 1 diabetes mellitus,Gestation diabetes mellitus and other special type ones; 2.In the past 3 months taking weight loss drugs, (including diet pills), oral any diabetes medication or insulin resistance in addition to the metformin outside; 3.With severe gastrointestinal disease, or be suffering from severe gastrointestinal diseases, such as: gastrointestinal ulcers, gastrointestinal bleeding, gastroparesis, pyloric stenosis, such as gastric bypass surgery; 4. Nearly one month have diabetes ketosis, ketosis acidosis ketosis high permeability diabetic coma, stress situation such as severe infection, operation; 5.With severe liver, renal insufficiency,Serum Creatinine (Cr)>132.6umol/L (1.5mg/dL); 6.Patients with clinically uncontrolled hypertension. (Blood pressure ≥160/100mmHg); 7.TG>5.65mmol/L; 8.Diabetic complication as the main symptom; 9.Psychopath, alcoholism and/or psychoactive substances, substance abuser and dependent; 10. pregnancy or lactation woman; 11.Allergic constitution.

Study execute time : From2013-4-1To

Interventions :	Group :	treatment group	Sample size :	96
	Intervention :	metformin +Jinlida granule 1bag, 3 times / day, warm boiling water	Intervention code :	
	Group :	matched group	Sample size :	96
	Intervention :	metformin	Intervention code :	

Countries of recruitment and research settings :	Country :	China	Province :	Jinlin	City :	Changchun City
	Institution hospital :	Affiliated Hospital of Changchun University of Traditional Chinese Medicine	Level of the institution :	Tertiary		
	Country :	China	Province :	Beijing	City :	Beijing
	Institution hospital :	Xiyuan Hospital, China Academy of traditional Chinese Medicine	Level of the institution :	Tertiary		
	Country :	China	Province :	Hebei	City :	Shijiazhuang
	Institution hospital :	TCM Hospital of Shijiazhuang City	Level of the institution :	Tertiary		
	Country :	China	Province :	Shanxi	City :	Taiyuan
	Institution hospital :	Shanxi Provincial Hospital of Traditional Chinese Medicine	Level of the institution :	Tertiary		
	Country :	China	Province :	Shanxi	City :	Taiyuan
	Institution hospital :	Affiliated Hospital of Shanxi College of Traditional Chinese Medicine	Level of the institution :	Tertiary		
	Country :	China	Province :	Hebei Province	City :	Shijiazhuang City
	Institution hospital :	People's Liberation Army Bethune International Peace Hospital	Level of the institution :	Tertiary		

Outcomes : Outcome : glycosylated hemoglobin

Collecting sample(s) from participants :	Sample Name :	Blood	Tissue :	Vein
	Fate of sample :	Destruction after use	Note :	

Recruiting status : Pending	Participant age :	Min age 18 years
		Max age 70 years

Randomization Procedure (please state who generates the random number sequence and by what method) :	Biometric unit provides a random number table	Gender : Both
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Blinding :

Calculated Results ater the Study Completed :

Organizer institution (leader institution) :

Data collection Institution :

Data management Institution :

Data analysis Institution :

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Support: 543 social work center

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Tips : it is recommended to use more than IE8.0 widescreen display resolution version using system.



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