Trial registration (2b)

Data Information	category
Primary registry and trial identifying number	Clinical Trials.gov: NCT02769572
Date of registration in primary registry	10 May, 2016
Secondary identifying numbers	/
Source(s) of monetary of material support	Ministry of Science and Technology of the Peoples' Republic of China
Primary sponsor	Ministry of Science and Technology of the Peoples' Republic of China
Secondary sponsor	Sichuan Provincial Department of Education
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Contact for scientific queries	Dr. Tang Chengdu University of Traditional Chinese Medicine Chengdu, Sichuan, China
Public title	Moxibustion in Osteoarthritis of the Knee
Scientific title	Moxibustion versus diclofenac sodium gel in treatment of knee osteoarthritis: A study protocol for a double-blinded, double-dummy, randomized controlled trial
Countries of recruitment	China
Health condition(s) or problem(s) studied	Knee osteoarthritis
Intervention(s)	Moxibustion group: treatment plus placebo gel; Control group: diclofenac sodium gel plus placebo moxibustion
Key inclusion and exclusion criteria	Inclusion criteria: (1) male or female, aged between 40 and 75 years, with knee osteoarthritis diagnosed according to American College of Rheumatology criteria;5 (2) radiological confirmation of osteoarthritis in one or both knees (Kellgren-Lawrence score 2 or 3); (3) had knee pain of longer than 3 months' duration; (4) the average severity of knee pain at least 3 points on a 10-point of VAS; (5) willingness to be randomly assigned and comply with our study protocol; (6) agreement to sign the consent form. Exclusion criteria: (1) pain in the knee may be caused by inflammatory, malignant, autoimmune disease or traumatic injury; (2) serious diseases including cancer, uncontrolled hypertension, diabetes mellitus requiring insulin injection; life-threatening cardiovascular or neurological events; chronic respiratory disease; bleeding

	disorders; clinically-active renal, hepatic or peptic ulcer diseases and serious mental diseases; (3) knee replacement surgery, arthroscopy of the affected knee within the past year, steroid or hyaluronic acid injection in the knee joints within the previous 3 months; (4) physiotherapy including acupuncture, cupping for knee pain during the previous 4 weeks; (5) previous experience with moxibustion treatment; (6) pregnant and lactating women; (7) participating in another clinical trial.
Study type	Interventional
	Allocation: randomized; Intervention model: parallel assignment; Masking: double blind; Study Classification: safety/efficacy;
	Primary purpose: treatment
	Phase III
Date of first enrollment	24, May, 2015
Target sample size	144
Recruitment status	Recruiting
Primary outcome(s)	The mean change in the global scale value of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) from baseline to 4 weeks.
Key secondary outcomes	The secondary outcomes include the mean changes in the WOMAC subscales (pain, stiffness, and function) at 2, 4, 8 and 12 weeks from baseline.