

Date	Apporval Number	Changes	Related revised documents
28 October 2016	B2016-204-01	/	/
8 December 2016	B2016-204-02	The amount of transport allowance was added to informed consents	1) informed consents
27 February 2017	B2016-204-03	inclusion criteria ("30 days post stroke" was revised to "30 days to one year post-stroke")	1) trial protocol; 2) Recruitment posters and documents
18 August 2017	B2016-204-04	Outcome measure (Functional Independence Measure was replaced by Barthel Index)	1) trial protocol; 2) Case report form; 3) SOP for investigators

## Ethics Committee of Guangdong Provincial Hospital of Chinese Medicine

## Approval Notice

No. of approval notice: B2016-204-01

Date	28 October 2016
Location	Room 2005-2006, 20 <sup>th</sup> Floor, Research Building, Guangdong Provincial Hospital of Chinese Medicine, No 111 Dade Road, Yuexiu District, Guangzhou, Guangdong Province, China
Funding	Not applicable
Research Project	Electro-acupuncture for post-stroke spasticity: a randomized controlled trial
Related documents	1. Ethics review application form (Version 1.0, 20 <sup>th</sup> September, 2016)
	2. Statement of economic interests (Zehuai Wen)
	3. Study protocol (Version 1.0, 20 <sup>th</sup> September, 2016)
	4. Case report form, Electro-acupuncture treatment record form, Screening questionnaire, General information record form (Version 1.0, 20 <sup>th</sup> September, 2016)
	5. SOP for investigators (Version 1.0, 20 <sup>th</sup> September, 2016)
	6. List of research fellows (Version 1.0, 20 <sup>th</sup> September, 2016) , Curriculum Vitae of principle investigator (Zehuai Wen)
	7. Notice and poster for recruitment (Version 1.0, 20 <sup>th</sup> September, 2016)
	8. Informed consent (Version 1.0, 20 <sup>th</sup> September, 2016)
Affiliation of principle Investigator	Guangdong Provincial Hospital of Chinese Medicine, China-Australia International Research Centre of Chinese Medicine
Research institutions	Guangdong Provincial Hospital of Chinese Medicine, RMIT University
Principle Investigator	Zehuai Wen
Members of ethics committee	Jun Liu, Xing Zeng, Xusheng Liu, Yan Li, Yini Luo, Bojian Chen, Yong Li, Likai Li
Comments of ethics review	According to the principle of “The Quality Control Standard for Drug Clinical Trials”, “Clinical Trial Ethics Review Guidelines” of China Food and Drug Administration, “Ethical Review Methods for Biomedical Research Involving Human Subjects” of National Health and Family Planning Commission of the People’s Republic of China, World Medical Association Declaration of Helsinki (2013), as well as International Ethical Guidelines for Biomedical Research Involving Human Subjects, the study “Electro-acupuncture for Post-stroke Spasticity: a randomized controlled trial” was approved by the Ethics Committee of Guangdong Provincial Hospital of Chinese Medicine.
Statement of ethics committee	The approval notice would also be stored for record. The ethics committee could be contacted if any disagreement on the feasibility of the trail (including the qualification of the investigators, equipment involved in the trial, or any other questions) is under concern.

	<p>The ethics committee should be informed if there is an early stop, suspending, or completion of the study. Any severe adverse event should be reported to the ethics committee in time. Any revision to the study protocol or informed consent, or change to the principle investigator should also be reported to the ethics committee and a new ethical review would be required. Besides, any action against the consent of participants needs to be reported to the ethics committee. Reports of research progress or conclusion report need to be submitted to the ethics committee at least one month before the due date.</p>		
Period of validity	28 <sup>th</sup> October 2016 to 28 <sup>th</sup> October 2018	Frequency of follow-up ethical review	Once a year
		Predicted Date for next ethical review	28 <sup>th</sup> October 2017
Contact telephone Number	+86-020-81887233 ext. 35943	Person to contact	Xiaoyan Li
Chief of the Ethics Committee	Jun Liu		
Guangdong Provincial Hospital of Chinese Medicine (Sealed)			
Date: 28 <sup>th</sup> October 2016			

## Ethics Committee of Guangdong Provincial Hospital of Chinese Medicine

## Approval Notice

No. of approval notice: B2016-204-02

Date	-		
Location	-		
Funding	-		
Research Project	Electro-acupuncture for post-stroke spasticity: a randomized controlled trial		
Documents for ethics review	1. Ethics review application form for revising documents		
	2. Informed consent (Version 2.0, 5 <sup>th</sup> December, 2016)		
Affiliation of principle Investigator	Guangdong Provincial Hospital of Chinese Medicine, China-Australia International Research Centre of Chinese Medicine		
Research institutions	Guangdong Provincial Hospital of Chinese Medicine, RMIT University		
Principle Investigator	Zehuai Wen		
Review form	Quick review		
Members of ethics committee	Yan Li		
Comments of ethics review	<p>According to the principle of “The Quality Control Standard for Drug Clinical Trials”, “Clinical Trial Ethics Review Guidelines” of China Food and Drug Administration, “Ethical Review Methods for Biomedical Research Involving Human Subjects” of National Health and Family Planning Commission of the People’s Republic of China, World Medical Association Declaration of Helsinki (2013), as well as International Ethical Guidelines for Biomedical Research Involving Human Subjects, the study “Electro-acupuncture for Post-stroke Spasticity: a randomized controlled trial” was approved by the Ethics Committee of Guangdong Provincial Hospital of Chinese Medicine.</p>		
Statement of ethics committee	<p>The approval notice would also be stored for record. The ethics committee could be contacted if any disagreement on the feasibility of the trail (including the qualification of the investigators, equipment involved in the trial, or any other questions) is under concern.</p> <p>The ethics committee should be informed if there is an early stop, suspending, or completion of the study. Any severe adverse event should be reported to the ethics committee in time. Any revision to the study protocol or informed consent, or change to the principle investigator should also be reported to the ethics committee and a new ethical review would be required. Besides, any action against the consent of participants needs to be reported to the ethics committee. Reports of research progress or conclusion report need to be submitted to the ethics committee at least one month before the due date.</p>		
Period of validity	28 <sup>th</sup> October 2016 to 28 <sup>th</sup>	Frequency of follow-up	Once a year

	October 2018	ethical review	
		Predicted Date for next ethical review	28 <sup>th</sup> October 2017
Contact telephone Number	+86-020-81887233 ext. 35943	Person to contact	Xiaoyan Li
Chief of the Ethics Committee	Jun Liu		
Guangdong Provincial Hospital of Chinese Medicine (Sealed)			
Date: 8 <sup>th</sup> December 2016			

## Ethics Committee of Guangdong Provincial Hospital of Chinese Medicine

## Approval Notice

No. of approval notice: B2016-204-03

Date	27 <sup>th</sup> February 2017
Location	-
Funding	-
Research Project	Electro-acupuncture for post-stroke spasticity: a randomized controlled trial
Documents for ethics review	1. Ethics review application form for revising documents 2. SOP for investigators (Version 2.0, 22 <sup>nd</sup> February, 2017) 3. Notice and poster for recruitment (Version 2.0, 22 <sup>nd</sup> February, 2017)
Affiliation of principle Investigator	Guangdong Provincial Hospital of Chinese Medicine, China-Australia International Research Centre of Chinese Medicine
Research institutions	Guangdong Provincial Hospital of Chinese Medicine, RMIT University
Principle Investigator	Zehuai Wen
Review form	Quick review
Members of ethics committee	Yan Li
Comments of ethics review	According to the principle of "The Quality Control Standard for Drug Clinical Trials", "Clinical Trial Ethics Review Guidelines" of China Food and Drug Administration, "Ethical Review Methods for Biomedical Research Involving Human Subjects" of National Health and Family Planning Commission of the People's Republic of China, World Medical Association Declaration of Helsinki (2013), as well as International Ethical Guidelines for Biomedical Research Involving Human Subjects, the study "Electro-acupuncture for Post-stroke Spasticity: a randomized controlled trial" was approved by the Ethics Committee of Guangdong Provincial Hospital of Chinese Medicine.
Statement of ethics committee	<p>The approval notice would also be stored for record. The ethics committee could be contacted if any disagreement on the feasibility of the trial (including the qualification of the investigators, equipment involved in the trial, or any other questions) is under concern.</p> <p>The ethics committee should be informed if there is an early stop, suspending, or completion of the study. Any severe adverse event should be reported to the ethics committee in time. Any revision to the study protocol or informed consent, or change to the principle investigator should also be reported to the ethics committee and a new ethical review would be required. Besides, any action against the consent of participants needs to be reported to the ethics committee. Reports of research progress or conclusion report need to be submitted to the ethics committee at least one month before the due date.</p>

Period of validity	28 <sup>th</sup> October 2016 to 28 <sup>th</sup> October 2018	Frequency of follow-up ethical review	Once a year
		Predicted Date for next ethical review	28 <sup>th</sup> October 2017
Contact telephone Number	+86-020-81887233 ext. 35943	Person to contact	Xiaoyan Li
Chief of the Ethics Committee	Jun Liu		
Guangdong Provincial Hospital of Chinese Medicine (Sealed)			
Date: 27 <sup>th</sup> February 2017			

## Ethics Committee of Guangdong Provincial Hospital of Chinese Medicine

## Approval Notice

No. of approval notice: B2016-204-04

Date	18 <sup>th</sup> August 2017
Location	-
Funding	-
Research Project	Electro-acupuncture for post-stroke spasticity: a randomized controlled trial
Documents for ethics review	1. Ethics review application form for revising documents
	2. Trial protocol (Version 3.0, 16 <sup>th</sup> August 2017)
	3. SOP for investigators (Version 3.0, 16 <sup>th</sup> August 2017)
	4. Case report form (Version 2.0, 16 <sup>th</sup> August 2017)
Affiliation of principle Investigator	Guangdong Provincial Hospital of Chinese Medicine, China-Australia International Research Centre of Chinese Medicine
Research institutions	Guangdong Provincial Hospital of Chinese Medicine, RMIT University
Principle Investigator	Zehuai Wen
Review form	Quick review
Members of ethics committee	Yini Luo
Comments of ethics review	<p>According to the principle of “The Quality Control Standard for Drug Clinical Trials”, “Clinical Trial Ethics Review Guidelines” of China Food and Drug Administration, “Ethical Review Methods for Biomedical Research Involving Human Subjects” of National Health and Family Planning Commission of the People’s Republic of China, World Medical Association Declaration of Helsinki (2013), as well as International Ethical Guidelines for Biomedical Research Involving Human Subjects, the study “Electro-acupuncture for Post-stroke Spasticity: a randomized controlled trial” was approved by the Ethics Committee of Guangdong Provincial Hospital of Chinese Medicine.</p>
Statement of ethics committee	<p>The approval notice would also be stored for record. The ethics committee could be contacted if any disagreement on the feasibility of the trail (including the qualification of the investigators, equipment involved in the trial, or any other questions) is under concern.</p> <p>The ethics committee should be informed if there is an early stop, suspending, or completion of the study. Any severe adverse event should be reported to the ethics committee in time. Any revision to the study protocol or informed consent, or change to the principle investigator should also be reported to the ethics committee and a new ethical review would be required. Besides, any action against the consent of participants needs to be reported to the ethics committee. Reports of research progress or conclusion report need to be submitted to the ethics committee at least one month before the due</p>



	date.		
Period of validity	28 <sup>th</sup> October 2016 to 28 <sup>th</sup> October 2018	Frequency of follow-up ethical review	Once a year
		Predicted Date for next ethical review	28 <sup>th</sup> October 2017
Contact telephone Number	+86-020-81887233 ext. 35943	Person to contact	Xiaoyan Li
Chief of the Ethics Committee	Jun Liu		
Guangdong Provincial Hospital of Chinese Medicine (Sealed)			
Date: 18 <sup>th</sup> August 2017			