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Effect of moxibustion on meridian in a warm needling model: A protocol for a prospective observational study

Submission date	**Recruitment status**	[_] Prospectively registered
30/05/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/06/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/08/2024	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Warm needling is a kind of traditional Chinese medicine (TCM) which uses burned moxa to generate warmth and exerts a therapeutic effect on human skin. It could improve deficiency-cold syndrome in TCM theory. Research has found that warm needling has effects on the immune system, endocrine (hormone) system, nervous system, lower urinary tract symptoms, and analgesic (pain relieving) effects. However, the mechanism of warm needling on the meridians has not been identified. In modern studies, the electric characteristic of the meridians has been discovered and the combination of semiconductor and TCM theory could explain the meridian phenomena through physics. However, there was no research exploring the relationship between the thermal effect and electric properties on the meridians. This study aims to explore the thermal effect on the electric characteristics of meridians in a warm needling model and provide a scientific explanation of TCM through the aspect of physics.

Who can participate?
Healthy volunteers over 20 years old

What does the study involve?
The participants receive acupuncture and then pain and electrical characteristics are measured. The investigators add the burned moxa to the acupuncture as a method of warm needling. After the moxa burned out, the investigators measure pain and electrical characteristics again.

What are the possible benefits and risks of participating?
Acupuncture, electric acupuncture, and warm needling are general practices. The chances of adverse side effects are less than 1%, which include minor bleeding or pain at needle insertion sites, nausea, sweating, and dizziness. Electric acupuncture is a complementary treatment that applies electricity to acupuncture and stimulates the meridians in the human body. Acupuncture will be done by qualified doctors. The device for electric acupuncture will apply voltage and current that are safe for the human body.

Where is the study run from?
1. Kaohsiung Chang Gung Memorial Hospital (Taiwan)
2. National Sun Yat-sen University (Taiwan)

When is the study starting and how long is it expected to run for?
August 2021 to December 2022

Who is funding the study?
Chang Gung Medical Research Fund (CMRPG8L1481)

Who is the main contact?
Chien Hung Lin
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Contact information

Type(s)
Principal investigator

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT05249010

Study information

Scientific Title
Effect of moxibustion on meridian in a warm needling model: A protocol for a prospective observational study

Study objectives
Current study hypothesis as of 20/09/2022:
The change in the physical properties of the acupuncture needle could produce different electric characteristics in the meridians and the phenomena could be explained by physics. However, there is no study investigating the relationship between temperature and electric characteristics in the meridians. The purpose of this study is to combine the theory of traditional Chinese medicine (TCM) and physics to explore the thermal effect on the electric characteristics of meridians in a warm needling model.

Previous study hypothesis:
Moxibustion has effects on analgesia and inflammation according to previous research. However, the mechanism of moxibustion and the way in which it affects meridians are not clear. In this study, it is hypothesized that moxibustion could produce an effect by changing electricity on the meridians.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/01/2022, Human Ethics Committee of Chang Gung Medical Foundation Institutional Review Board (199, Tung Hwa North Road, Taipei, Taiwan, 10507, Republic of China; +886 (0)3 3196200, ext. 3713; ccyi@cgmh.org.tw), ref: 202101924A3

Primary study design
Observational

Study design
Prospective observational study

Study type(s)
Other

Health condition(s) or problem(s) studied
The effect of warm needling on the meridian

Interventions
Current interventions as of 20/09/2022:
All participants receive acupuncture and warm needling. First, participants receive acupuncture and then measure the visual analog scale (VAS) and electric characteristics with the semiconductor analyzer Agilent B1500A. The investigators add the burned moxa onto the acupuncture as a method for warm needling and then measure the VAS and electric characteristics again.

Previous interventions:
All participants receive acupuncture and moxibustion. First, participants receive acupuncture and then measure the visual analog scale (VAS) and electric characteristics with the semiconductor analyzer Agilent B1500A. The investigators add the burned moxa onto the acupuncture as a method for moxibustion and then measure the VAS and electric characteristics again.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Current primary outcome measures as of 20/09/2022:
1. Electric current measured using the Agilent B1500A device after the intervention of acupuncture (baseline data) and warm needling (post warm needling data)
2. Voltage measured using the Agilent B1500A device after the intervention of acupuncture (baseline data) and warm needling (post warm needling data)

Previous primary outcome measures:
1. Pain measured using the visual analog scale (VAS) immediately after the intervention of acupuncture (baseline data) and moxibustion (post moxibustion data)
2. Electric current measured using the Agilent B1500A device after the intervention of acupuncture (baseline data) and moxibustion (post moxibustion data)
3. Voltage measured using the Agilent B1500A device after the intervention of acupuncture (baseline data) and moxibustion (post moxibustion data)

Key secondary outcome(s)
Added 20/09/2022:
Pain measured using the visual analog scale (VAS) immediately after the intervention of acupuncture (baseline data) and warm needling (post warm needling data)

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. At least 20 years old
2. Agree to the informed consent

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Under 20 years old
2. Pregnant or breastfeeding women
3. Those with an empty stomach before the study
4. A tendency toward bleeding with thrombocytopenia or history of platelets <20000 or a user of an anti-platelet drugs

Date of first enrolment
29/03/2022

Date of final enrolment
31/12/2022

Locations

Countries of recruitment

Taiwan

Study participating centre
Chang Gung Memorial Hospital
No. 123, Dapi Rd., Niaosng Dist
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83342

Sponsor information

Organisation
Kaohsiung Chang Gung Memorial Hospital

ROR
https://ror.org/00k194y12

Funder(s)

Funder type
Research organisation

Funder Name
Chang Gung Medical Research Fund

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Chien-Hung Lin (b9505027@cgmh.org.tw).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		25/11/2022	08/08/2024	Yes	No
Participant information sheet	version 3		31/05/2022	No	Yes