PARTICIPANT INFORMATION SHEET AND CONSENT FORM

STUDY INFORMATION

Protocol Title:

A randomized controlled trial of electroacupuncture in the management of patients with axial Spondyloarthritis in Singapore (E-AcuSpA)

Principal Investigator:

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Consultant

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PURPOSE OF THE RESEARCH STUDY

You are being invited to participate in a research study. Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the consent form. You will be given a copy of this document to take home with you.

The purpose of this study is to understand the effectiveness, safety and cost-effectiveness of electroacupuncture in the management of patients with Axial Spondyloarthritis (AxSpA). We hope to understand whether electroacupuncture will result in better management of symptoms such as pain and fatigue in patients with AxSpA as compared to manual acupuncture. Acupuncture is a medical technique unique to Traditional Chinese Medicine. Through the use of silver needles, it serves to activate blood circulation, regulate qi and blood, restore yin and yang, support healthy qi and eliminate pathogenic factors. For manual acupuncture, needles are stimulated manually to achieve de qi (a compositional sensation including soreness, numbness, distention and heaviness). For electroacupuncture, electrical stimulation is administered through acupuncture needles. You were selected as a possible participant in this study because you have AxSpA.

This study will recruit 100 participants from Singapore General Hospital.

STUDY PROCEDURES AND VISIT SCHEDULE

If you agree to take part in this study, you will be randomised to either electroacupuncture arm or manual acupuncture arm. Randomisation means assigning you to one of the groups by chance, like tossing a coin or rolling dice.

If you agree to take part in this study, we would like to seek your permission to use your clinical data (eg gender, height, weight, ethnicity, severity of disease, medications etc) for research purposes. We will also collect data of costs incurred by you in using hospital services in Singapore General Hospital (e.g. consultation costs, costs of laboratory tests, radiological tests and medication costs) from the business office in Singapore General Hospital so that we can understand whether the electroacupuncture and/or acupuncture can reduce the cost incurred for using hospital services.

If you agree to take part in this study, you will be asked to do questionnaires at baseline, 3rd week, 6th week, 9th week, 12th week, and 24th and 52nd week duration. Your participation in the study will last for a year. You will be either referred to undergo 20 sessions of electroacupuncture or to undergo 20 sessions of manual acupuncture at Singapore Thong Chai Medical Institute and/or at Singapore General Hospital depending on the availability. Each acupuncture session will last around 30 minutes. For the electroacupuncture, the dense-sparse stimulation mode will be used for this study. The current used is based on the tolerance of each patient. For patients who report weak or no sensation at the point of stimulation, the electrical flow can be increased gradually, or the apparatus switched off for 1-2 minutes and then restarted. The voltage of the electric current can range from 6 to 21 volts. Your condition will be closely monitored by the TCM physician as well as the rheumatologist. Interview will be conducted at week 12 (after completing acupuncture sessions) to find out the feasibility and acceptability of the acupuncture treatment. To ensure accuracy in data interpretation, the session will be audio-taped.

In addition, your de-identified data collected during the study may be kept for future research beyond the completion of the study. For this purpose, consent for future research will be sought from you.

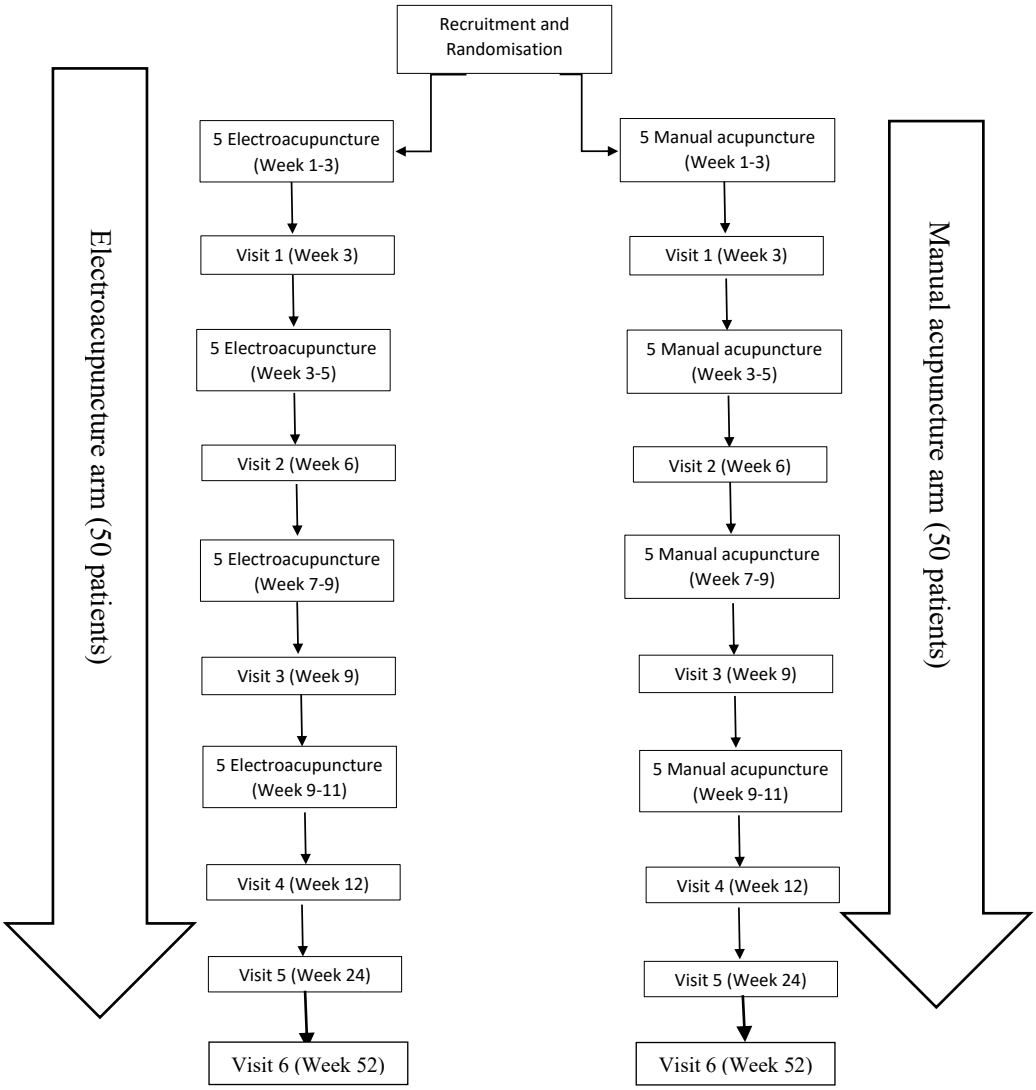
Schedule of visits and procedures:

Visit 1, 2, 3, 4, 5 and 6 (week 3, week 6, week 9, week 12, week 24, week 52): Questionnaire

Visit 2, 4, 5 and 6 (week 6, week 12, week 24, week 52): Routine rheumatology visit

You will be required to undergo 20 sessions of acupuncture in total in addition to the above visit.

Diagram representation of Visit Schedules:



YOUR RESPONSIBILITIES IN THIS STUDY

If you agree to participate in this study, you should:

- Go for the required acupuncture session as instructed and follow the advice given to you by the study team.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the study team member to reschedule as soon as you know you will miss the appointment.
- Inform the Principal Investigator as soon as possible about any side effects that you may have encountered.
- Be prepared to visit the hospital and undergo all the procedures that are outlined above.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the study team member to reschedule as soon as you know you will miss the appointment.

WHAT IS NOT STANDARD CARE OR EXPERIMENTAL IN THIS STUDY

The study is being conducted because TCM, in particular, electroacupuncture, is not yet proven to be a standard treatment in patients with AxSpA. We hope that your participation

will help us to determine whether electroacupuncture is more effective than manual acupuncture.

Using clinical data for research and the use of electroacupuncture or manual acupuncture, is not part of standard care. Standard care for AxSpA includes medications such as nonsteroidal anti-inflammatory drugs (NSAIDs) or biologics. Randomization is only done for research studies.

POSSIBLE RISKS, DISCOMFORTS AND INCONVENIENCES

- There is potential risk of skin injuries and infections but the risk is very low and only trained acupuncturist will see you.
- The most severe side effect is fainting due to needle phobia. Please let us know in advance so that the TCM physician can manage accordingly.
- Although TCM acupuncture is a relatively safe procedure, there may be some adverse events, which may include fainting, bent or broken needle, local pain, slight bleeding.

POTENTIAL BENEFITS

If you participate in this study, you may not expect any immediate benefits from the study. Your participation will contribute to the medical knowledge about the use of TCM, in particular, electroacupuncture, in the management of AxSpA. The results of the study are likely to be published in medical journals.

IMPORTANT INFORMATION FOR FEMALE PARTICIPANTS

The effect of electroacupuncture and manual acupuncture on a baby's development is not known. Therefore, pregnant and breast-feeding women may not take part in this study. Women who have a chance of becoming pregnant must have a negative pregnancy test at study entry and use birth control during the study. If you become pregnant during this study, you must call your doctor or the Principal Investigator immediately and stop receiving electroacupuncture or manual acupuncture.

ALTERNATIVES

If you choose not to take part in this study, the alternative is to have what is considered standard care for your condition. In our institution this would be medications such as nonsteroidal anti-inflammatory drugs (NSAIDs) or biologics. These medications have been licensed for treatment of your medical condition. Potential risks of NSAIDs include side effects of the gastrointestinal tract, heart disease and renal impairment; whilst there is increased risk of infection with biologics.

COSTS OF PARTICIPATION

If you take part in this study, the following will be performed at no charge to you:

1. Electroacupuncture or manual acupuncture

If you take part in this study, you still have to pay for the following as part of your routine care:

1. Routine blood tests

2. Chest X-rays, X-rays of hands, feet, sacroiliac joints and back

3. Other routine investigations as indicated

4. Consultations

You will be reimbursed for your time, inconvenience and transportation costs as follows: $60 for each TCM session or data collection after the baseline data. Payment will be paid on the 3rd, 6th, 9th and 12th week, 24th week and 52nd week cumulatively. The data collection point will be held on the day of your consultation to minimise inconvenience as far as possible.

INCIDENTAL FINDINGS

There will not be any incidental findings arising in this research. “Incidental findings” are findings that have potential health or reproductive importance to research participants like you and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study.

PARTICIPANT’S RIGHTS

Your participation in this study is entirely voluntary. Your questions will be answered clearly and to your satisfaction.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you (or your legal representative, if relevant) will be informed in a timely manner by the Principal Investigator or his/her representative and will be contacted for further consent if required.

By signing and participating in the study, you do not waive any of your legal rights to revoke your consent and withdraw from the study at any time.

WITHDRAWAL FROM STUDY

You are free to withdraw your consent and discontinue your participation at any time without prejudice to you or effect on your medical care. If you decide to stop taking part in this study, you should tell the Principal Investigator.

If you withdraw from the study, or the acupuncture treatment is stopped for any reason,

- There will be no consequences
- Please inform the study team member as well as the TCM physician so that we can discharge you from TCM management

However, the data that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

Your doctor, the Principal Investigator may stop your participation in the study at any time for one or more of the following reasons:

- Failure to follow the instructions of the Principal Investigator and/or study staff.
- The Principal Investigator decides that continuing your participation could be harmful.
- You need treatment not allowed in the study.
- The study is cancelled.

RESEARCH RELATED INJURY AND COMPENSATION

If you follow the directions of the Principal Investigator of this research study and you are injured due to the trial substance or research procedure given under the plan for the research study, our institution will provide you with the appropriate medical treatment.

Payment for management of the normally expected consequences of your treatment will not be provided by the Singapore General Hospital.

You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages where you can prove negligence.

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

Your participation in this study will involve the collection of Personal Data. Personal Data collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. Only your Investigator(s) will have access to the confidential information being collected.

However, the Regulatory Agencies, Institutional Review Board and Ministry of Health will be granted direct access to your original medical records to check study procedures and data, without making any of your information public.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by Singapore General Hospital, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties.

“Personal Data” means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. Examples of personal data include medical conditions, medications, investigations and treatment history.

Research arising in the future, based on this “Personal Data”, will be subject to review by the relevant institutional review board.

Data collected and entered into the Data Collection Form(s) are the property of Singapore General Hospital. In the event of any publication regarding this study, your identity will remain confidential.

By participating in this research study, you are confirming that you have read, understood and consent to the SingHealth Data Protection Policy, the full version of which is available at www.singhealth.com.sg/pdpa.

WHO TO CONTACT IF YOU HAVE QUESTIONS REGARDING THE STUDY

If you have questions about this research study or in the case of any injuries during the course of this study, you may contact the Principal Investigator *(Dr Warren Fong, Tel: 6326 5560 or 8223 5413).*

WHO HAS REVIEWED THE STUDY

This study has been reviewed by the SingHealth Centralised Institutional Review Board for ethics approval.

If you have questions about your rights as a participant, you can call the SingHealth

Centralised Institutional Review Board at 6323 7515 during office hours (8:30 am to 5:30pm).

If you have any feedback about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.

CONSENT FORM

Details of Research Study

Protocol Title:

A randomized controlled trial of electroacupuncture in the management of patients with axial Spondyloarthritis in Singapore (E-AcuSpA)

Principal Investigator:

Dr Fong Weng Seng Warren

Department of Rheumatology and Immunology

Level 4 Academia

20 College Road

Singapore 169856

Tel: 6326 5560 or 8223 5413

I agree to participate in the research study as described and on the terms set out in the Participant Information Sheet.

I have fully discussed and understood the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to ask questions about this study and have received satisfactory answers and information.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons and without my medical care being affected.

By participating in this research study, I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

Consent for the Use of Data for Future Research

Please indicate your options by indicating a tick (√) on the checkboxes:	**Yes**	**No**
Do you consent for your data to be used for future research?	☐	☐

Name of participant	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The study has been explained to the participant/ legal representative in

_____ by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this informed consent form had the study fully explained in a language understood by him/ her and clearly understands the nature, risks and benefits of his/ her participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative giving the consent.
- I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Witnessed by: _____ _____
Name of witness Date of signing

_____
Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant or legal representative thumbprint). After the written consent form and any written information to be provided to participant, is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this consent form had the study fully explained and clearly understands the nature, risks and benefits of his/ her/ his ward's/ her ward's participation in the study.

_____ _____ _____
Name of Investigator/ Person obtaining consent Signature Date