

# Effects of Laser Acupuncture on Constipation in Patients With Advanced Cancer: Study Protocol for a Double-blinded, Randomized Controlled Trial

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## Study protocol

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# Abstract

## Background

Constipation is a common, uncomfortable, and frustrating complication in patients with advanced cancer which in turn affects the patient's quality of life. The aim of this study is to investigate the effects of laser acupuncture on constipation.

## Methods

This is a prospective, single-center, double-blinded, randomized controlled trial study. A sample of 74 participants will be randomly assigned to either the verum or the sham laser acupuncture group in a 1:1 ratio. The participants will receive laser acupuncture or sham laser acupuncture once a day for consecutive six days on eight acupoints (LI4, LI11, PC6, ST36, ST37, ST39, SP4, and SP9). The number of complete spontaneous bowel will be used primarily for the evaluation, and symptoms of constipation, comfort levels during defecation, and colonic motility will be also be measured. Data will be analyzed using the *chi-square* test or *t*-test. Analysis of covariance will be used to examine the differences on symptoms of constipation between two groups and adjusted for their respective baseline levels.

## Discussion

This trial may provide evidence for improving the short-term benefit for advanced cancer patients by relieving the symptoms caused by constipation. As a result, further reduce the usage of medications, and lower the side effects due to medications.

**Trial registration:** ClinicalTrials.gov, NCT04318808. Registered on 24 March 2020.

## Background

Constipation can be defined as reduced frequency of defecation and stool passage, hardness of the stool, and the feeling of incomplete evacuation [1]. The clinical symptoms of constipation include straining during defecation, bloating, abdominal discomfort, infrequent bowel movements, hard or lumpy stools, a sense of incomplete evacuation, defecation requiring manual maneuvers to complete, and bowel movements less than three times per week [2,3]. These symptoms often adversely affect the patient's quality of life [2].

Constipation is a common, uncomfortable, frustrating, and underestimated complication for patients with advanced cancer. Approximately 40-66% of patients with advanced cancer receiving palliative care are suffering from constipation [4]. Medications, poor appetite, decreased fluid intake, and immobility are the main causes of constipation in these patients [5]. Untreated constipation may lead to several complications [6], such as inadequate absorption of oral drugs, fecal impaction, rectal tearing, rectal fissure, hemorrhoids, bowel obstruction, and intestinal perforation [7].

Before treating these patients with laxatives or enema, we usually suggest non-pharmacological interventions such as diet adjustment, change of lifestyle, or increase of exercise to help relief constipation symptoms. However, due to different conditions of patients, such conservative treatments may not always be applicable. Therefore, when non-pharmacological interventions are ineffective for relief of constipation, pharmacological treatments are then usually the next option recommended for short-term symptom relief [8,9].

However, when we turn to medical treatments, side effects and adverse events have been known to be reported, including diarrhea, metabolic disturbances, colonic damage, and exacerbated constipation [5,10]. As the result, various non-pharmacological treatments are widely used for the prevention and treatment of constipation, such as acupressure [5], acupuncture [10,11], electro-acupuncture [12], moxibustion [13], and massage [14]. These treatments mentioned above have the advantage of being safer and non-pharmacological, thus are considered to be great alternative treatments when treating constipation.

According to a review article, it was concluded that acupuncture and electro-acupuncture, followed by herbal medicine as the third, were the most commonly used complementary and alternative therapies for constipation [15]. Another multicenter randomized controlled trial involving 684 patients with chronic functional constipation, concluded that acupuncture treatments were as effective as using mosapride in improving stool frequency and consistency in chronic functional constipation [16]. In the light of a trial involving 1075 participants throughout 15 hospitals in China, showed electroacupuncture increases spontaneous complete bowel movements and these effects can persist throughout 12 weeks [17]. On the basis of a systemic review and meta-analysis of 28 RCTs involving 3525 participants, concluded that acupuncture is safe and effective for chronic functional constipation even compared to pharmacological treatments, and can increase stool frequency, relief constipation symptoms, and improve stool formation as well [11].

Even though acupuncture is one of the most popular complementary and alternative interventions used [18], it is still considered invasive, and sometimes painful and even stressful to patients. A variety of factors may cause differences in the effects of acupuncture treatment, including physicians, acupuncture technique, acupoint specificity, and psychological factor [19]. Laser acupuncture, on the other hand, provides a safer, pain-free, non-invasive alternative technique that involves stimulation of traditional acupoints with low-intensity, non-thermal laser irradiation, and is also effective with less time needed than traditional acupuncture. [18,24] Laser acupuncture also eliminates the risks of complications that acupuncture might lead to, such as pneumothorax [20], hematoma [21], perforation [22], or acupuncture site infection [23].

Several systematic reviews indicated that laser acupuncture shows promising results in relieving symptoms of various health problems such as knee osteoarthritis [25], musculoskeletal pain [26], and carpal tunnel syndrome [27]. Nevertheless, best to our knowledge, no reports specifically focused on the effect of laser acupuncture on constipation in patients with advanced cancer are found in the English

literature. The research hypothesis is that laser acupuncture is effective for constipation in patients with advanced cancer. Therefore, the aim of this study is to investigate the effects of laser acupuncture on constipation, to offer a better and simpler therapy for treating constipation in advanced cancer patients.

## **Methods/design**

### **Aims and objectives**

This study aims to provide evidence for improving the short-term benefit for advanced cancer patients by relieving the symptoms caused by constipation. As a result, further reduce the usage of medications, and lower the side effects due to medications.

### **Study design**

A single-center, double-blinded, randomized controlled trial study will be conducted at Kaohsiung Chang Gung Memorial Hospital (KCGMH) between March 2020 and February 2022. Participants will be enrolled from the hospice unit at KCGMH. Participants met the inclusion criteria and provide written informed consent will be randomly assigned to experimental group (laser acupuncture [LA]) and control group (sham laser acupuncture [SLA]) in 1:1 ratio. Experimental group will be treated by laser acupuncture, while the control group will receive laser acupuncture without laser output. Participants in both groups will receive conventional treatments such as laxatives, which are evaluated and managed by their hospice physicians. All participants will receive laser acupuncture or sham laser acupuncture once a day for consecutive six days after enrollment.

The study design has been written in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) and Consolidated Standards of Reporting Trials (CONSORT) 2010 guidelines [30, 31]. The overall schematic chart and study schedule are shown in figures 1 and 2, respectively.

### **Patient involvement**

Patients and their family were involved in the design and conduct of this trial. During the planning of this trial, priority of patient's needs, introduction of laser acupuncture, choice of outcome measures, methods of recruitment, and dissemination plans of this study were informed by discussions with patients and their family through interviews and group-based patient education.

### **Participants**

The information of the trial will be provided by hospice physician. Participants' eligibility in the study is assessed by hospice physicians at KCGMH. All participants will provide written consent after receiving an

oral explanation of the objectives and procedures of the study by their hospice physicians. All participants with constipation are managed by the hospice physicians' expertise who have no information about the allocation results.

### **Inclusion criteria**

Subjects are eligible to participate if they meeting all of the following criteria: (1) age of 20 years or older; (2) conscious clear and able to communicate; (3) principal diagnosis of advanced cancer ; (4) diagnosis of constipation by the hospice medical team; (5) treated with laxatives for at least 1 week but still have symptoms of constipation; (6) consent to participate in the study.

### **Exclusion criteria**

Subjects will be excluded if they meet any of the following criteria: (1) unconscious or delirium; (2) intestinal obstruction; (3) active gastrointestinal bleeding; (4) active intraabdominal infection; (5) local skin infection on the acupoints or limb amputee.

### **Dropout criteria**

Participants will be dropped from the trial under the following conditions: (1) unstable vital signs and in need of first aid during study period; (2) the clinical conditions are deteriorated and determined unsuitable to continue this study by medical staff; (3) participants can decide to withdraw from the trial at any time.

### **Recruitment strategies**

The main recruiting way is the inpatients from the hospice unit of KCGMH. Hospice physicians provide the information of this study to participants and then assess the participants' eligibility to participate in the study.

### **Blind and randomization**

All the participants are informed that they will receive laser acupuncture in addition to the conventional treatment and assess the efficacy of laser acupuncture. The device appearance of laser acupuncture is the same in both LA and SLA groups, except energy output. The participants are unable to recognize whether they are being treated or not, because the laser acupuncture is a low-intensity and non-thermal laser irradiation. Participants will be randomly allocated to LA or SLA group in a 1 : 1 ratio using computer-generated random numbers. Randomization will be performed by an independent researcher who is not involved in the inclusion or exclusion process, treatment and assessment procedures. The trial participants, outcome assessors, and data analysts will be blinded after assignment to interventions using label A and B for the 2 groups till the trial completed. After completing the intervention period, the participants can be allowed to know which group they are assigned to if they want.

### **Intervention**

All participants will still receive conventional treatment depended on hospice physicians' expertise. The participants in each group will undergo real LA or sham LA treatment once a day for six consecutive days, using a gallium aluminum arsenide LaserPen (maximal power, 150 mW; wavelength, 810 nm; area of probe, 0.03 cm<sup>2</sup>; power density, 5W/cm<sup>2</sup>; pulsed wave; and Bahr frequencies [B1: 599.5Hz, B2: 1199Hz, B3: 2398Hz, B4: 4776Hz, B5: 9552 Hz, B6: 19,104Hz, and B7: 38,208Hz]; RJ-Laser, Reimers & Janssen GmbH, Waldkirch, Germany).

Acupoints and manipulations are the same in both the experimental and the control groups. The participants in the control group will receive sham laser acupuncture treatment, without any laser output, while the participants in the experimental group will sequentially receive 0.375J of energy at each of the following acupoints: LI4 (Hegu, B3), LI11 (Quchi,B2), PC6 (Neiguan, B3), ST36 (Zusanli, B2), ST37 (Shangjuxu, B2), ST39 (Xiajuxu, B2), SP4 (Gongsun, B3), SP9 (Yinlingquan, B2). The laser treatment will be applied to each point for 5 seconds, to deliver a total treatment dose of 4.5J/cm<sup>2</sup>. All acupoints are selected and localized according to the WHO Standardized Acupuncture Point Location guidelines [28]. In all the subjects, the laser application will be performed by the same experienced physician who has sufficient training and is a licensed Chinese medicine practitioner in Taiwan. Protective goggle and laser shield are used by the operator and the patient to inhibit visual perception during laser acupuncture. Although LA therapy is noninvasive, in order to improve adherence to intervention, we will explain in detail the indications and advantages of LA and establish a good relationship with patients.

### **Outcomes measurements**

During the trial, participants will record in daily diaries the complete spontaneous bowel movements (CSBMs), symptoms of constipation and change of the diet and exercise. Spontaneous bowel movement (SBM) is defined as a stool not induced by rescue medication, whereas a CSBM is defined as an SBM associated with a sensation of complete evacuation.

#### ***Primary outcome***

The primary outcome is the number of CSBMs in the past one week. The data will be recorded at baseline and at day 7 after treatment.

#### ***Secondary outcome***

The secondary outcomes are symptoms of constipation, comfort levels during defecation, and colonic motility. These outcomes will be assessed at the baseline, day 1, day 3, day 5, and day 7.

For the symptoms of constipation, we use five items measurement based on a previously published study [5], including straining during defecation, abdominal pain during defecation, hard stools, sensation of incomplete evacuation, and sensation of anorectal obstruction or blockage. Each item is rated on a four-point Likert scale that ranges from 1-4 points, which a higher score indicates more severe symptom. The comfort level during defecation will be estimated using a 10-cm visual analogue scale with points of 0-10 points, with a higher score indicates a higher level of discomfort during defecation. The frequency of

colonic motility in times per minute will be measured by auscultation of the lower right abdomen with a stethoscope.

### **Sample size calculation**

There is lacking previous study of laser acupuncture for the treatment of constipation in patients with advance cancer. Determination of the necessary sample size is based on a previous study of the effects of electroacupuncture for functional constipation [29]. The mean  $\pm$  standard deviation of constipation symptom score at week 2 was  $6.81 \pm 2.62$  in acupuncture group and  $8.44 \pm 2.61$  in control group. Anticipating a power of 95% ( $1-\beta=0.95$ ), statistical significance ( $\alpha=0.05$ ) of 95% and a dropout rate of 10%, a total of 74 participants is required using G\*power analysis in this study.

### **Statistical analysis**

The data of the participants who complete the 6-day intervention will be expressed as frequencies, percentages or mean  $\pm$  standard deviation. The differences between the LA and SLA groups are compared using the *chi-square* test or *t*-test. Analysis of covariance will be used to examine the differences on symptoms of constipation, comfort levels during defecation, and colonic motility between the LA and SLA groups, adjusted for their respective baseline levels. Differences are considered to be significant at a *p* value of  $<.05$ . All analyses will be performed by using the IBM SPSS Statistics package version 24.0 (SPSS Inc., Chicago, IL, USA). The missing data of participants who do not complete the 6-day intervention will be excluded in the analysis.

### **Adverse events monitoring**

Data monitoring committee (DMC) is not needed because laser acupuncture is general practice and noninvasive intervention. Nevertheless, the adverse reactions such as diarrhea, abdominal pain, fainting during laser acupuncture treatment will be monitored during the trial period. Any suspected adverse events will be reported by the patients' hospice physicians to the researcher. Adverse events will be managed by the patient's hospice physician, and other specialist doctors will be consulted if necessary. The researchers have the right to terminate the trial if any severe adverse events are noted. Independent audits are performed by the Institutional Review Board of the Chang Gung Medical Foundation every six months.

### **Privacy and Confidentiality**

There will be a study code that represents the identity of patient. This code will not show patient's name, identity card number, and address. For the results and diagnosis of participants' visit, the study investigators will maintain a confidential attitude and be careful to maintain their privacy. If the investigators publish the results, patient's identity will remain confidential.

## **Discussion**

There are promising effects of acupuncture and acupressure in the treatment of constipation, moreover, there is also evidence supporting that laser acupuncture can relieve symptoms of various health problems. This trial seeks a better and simpler alternative therapy, providing the advantages of laser acupuncture, which is safer, pain-free, and non-invasive. The results of this study can provide the evidence of laser acupuncture intervention in advanced cancer patients with constipation. Our expectation for laser acupuncture is to improve the short-term benefit for advanced cancer patients by relieving the symptoms of constipation, and even further reduce the usage and adverse events of regular and rescued laxatives.

Some limitations of this study are as follows. First, although participants with diagnosis of intestinal obstruction will be excluded, for participants with advanced gastrointestinal cancer may affect the severity of constipation and the effect of laser acupuncture. The measurement of symptoms of constipation at baseline may have recall bias because most people don't record their bowel movements every day. Thus, we will check symptoms of constipation from medical records if any. Moreover, the severity of symptoms other than constipation such as physical and psychological symptoms and multiple organ failures is also associated with the effect of laser acupuncture.

## **Trial Status**

This trial was registered on March 24, 2020 (registration number NCT04318808, ClinicalTrials.gov) <https://www.clinicaltrials.gov/ct2/show/NCT04318808>. The data recruitment began on March 10, 2020 and the trial is ongoing. The recruitment will be completed in approximately February 2022. The study is expected to be completed in July 2022. Protocol version 3.0, date: 28 May 2020.

## **List Of Abbreviations**

KCGMH Kaohsiung Chang Gung Memorial Hospital

LA laser acupuncture

SLA sham laser acupuncture

CSBM complete spontaneous bowel movement

SBM Spontaneous bowel movement

DMC Data monitoring committee

## **Declarations**

**Ethics approval and consent to participate**



This protocol has been reviewed and approved by the Institutional Review Board of the Chang Gung Medical Foundation (IRB no. 201901437A3). This study is conducted in accordance with the principles of the Declaration of Helsinki. Both verbal and written forms of detailed information about the trial will be given before participation by hospice physicians at KCGMH. All participants will voluntarily sign the informed consent that has been approved by the ethics committee prior to enrollment. Personal information about potential and enrolled participants will be collected, shared, and maintained in an independent closet in order to protect confidentiality before, during, and after the trial. We will present the results and submit for publication in peer-reviewed journals. CTC and CTL will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators

### **Consent for publication**

Not applicable

### **Availability of data and materials**

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

### **Competing interests**

The authors declare that they have no competing interests

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### **Author's Contribution**

JMC and CTL designed the protocol and drafted the manuscript. CTC and BYW will analyze the data. CTC and CTL will interpret the data. BYW and YHC will supervise the statistical analysis. All authors were involved in editing the manuscript, and all read and approved the final text of the manuscript.

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Not applicable

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## Figures

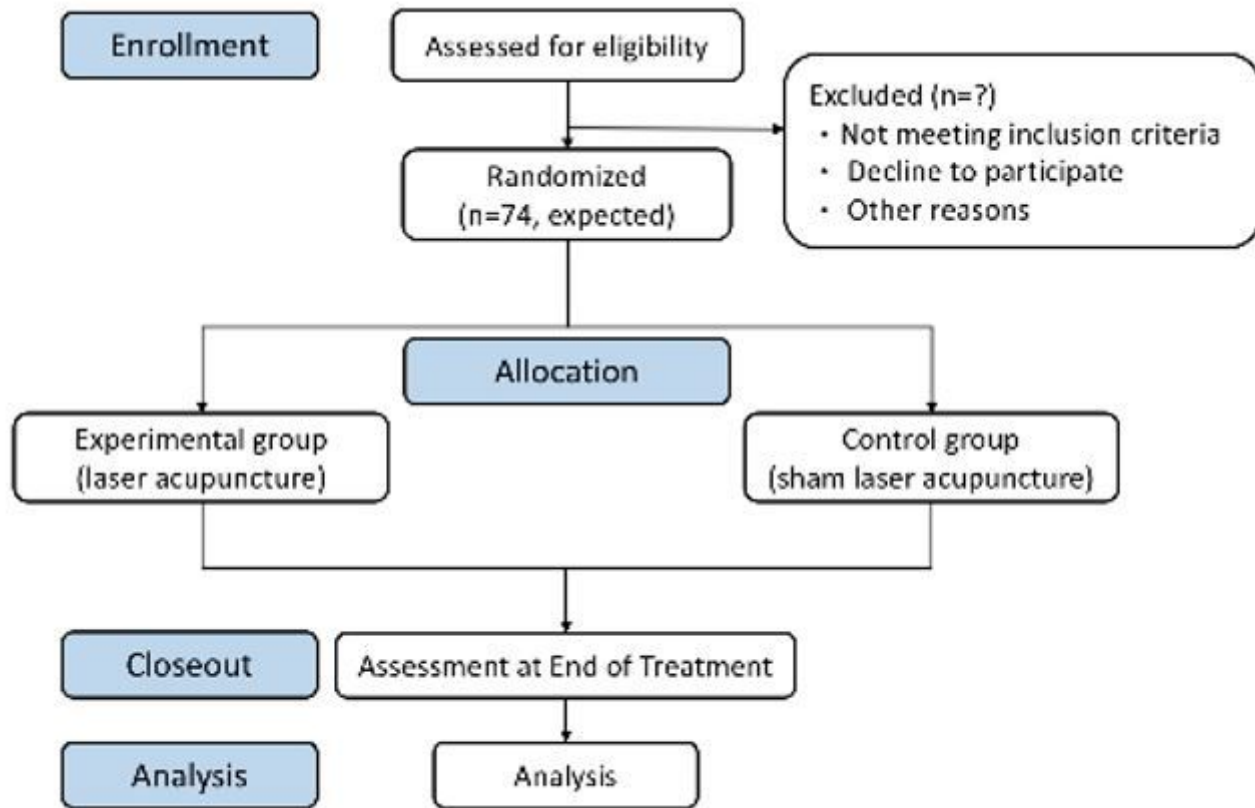


Figure 1

Flow chart of the trial. The template is from the CONSORT 2010 flow diagram [30].

	Consent & Randomization	Treatment						
		VISITS	V2	V3	V4	V5	V6	V7
TIMEPOINT	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
<b>ENROLLMENT:</b>								
Informed consent	X							
Basic and clinical characteristics	X							
Vital sign	X							
Activity level	X							
Medication use	X							
random allocation	X							
<b>INTERVENTIONS:</b>								
Laser acupuncture		←-----→						
Sham laser acupuncture		←-----→						
<b>ASSESSMENTS:</b>								
number of complete spontaneous bowel movements	X	X						X
Symptoms of constipation	X	X		X		X		X
Comfort level during defecation	X	X		X		X		X
Colonic motility	X	X		X		X		X

## Figure 2

Study schedule of enrollment, inventions, and assesments. The template is from the SPIRIT 2013 statement [31].

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [SPIRITChecklist1214.docx](#)