Acupuncture for cancer pain: a pilot pragmatic randomized controlled trial

Case Report Form

(Translated from Chinese)

Participant ID：_____

Name of Participant：_____

Name of investigator：_____

Date of recruitment：__ __ (Day) __ __ (Month) __ __ __ __ (Year)

Date of trial completion：__ __ (Day) __ __ (Month) __ __ __ __ (Year)

Research Stages: Assessment Table

Assessment Items \ Day	0	1	2	3	4	5	6	7	14	21
General information*	☐									
Analgesic consumption	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
NRS	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
FBP	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
AEs	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Acupuncture therapy		☐	☐		☐		☐			
Drop-outs with reasons		☐	☐	☐	☐	☐	☐	☐	☐	☐
Other medications used		☐	☐	☐	☐	☐	☐	☐	☐	☐

Notes：Items with "☐" are required to be checked. Please tick the correspondent boxes ("☑") once assessment is completed. *General information includes basic characteristics of patients, vital signs, history of allergy and any other conditions, clinical and pathological diagnosis of cancer; treatment received for cancer and other complications or side effects; NRS: Numerical rating scale; FBP: Frequency of breakthrough pain and rescue medication; AEs: adverse events.

Selection criteria

Inclusion criteria	Yes	No
1. Cancer confirmed by histological or cytological examination	☐	☐
2. NRS⩾4 for the past 24 hours	☐	☐
3. Age ≥ 18	☐	☐
4. Signed informed consent	☐	☐

If any of the above items is answered with "No", the patient can not be recruited into the trial.

Exclusion criteria	Yes	No
1. Severe and unstable physical illnesses, such as disorders of consciousness, dyspnoea, acute myocardial infarction, acute heart failure, acute renal failure, diabetic ketoacidosis, as well as any other critical conditions or acute stage of disorders	☐	☐
2. Lactation, pregnancy or intend to be pregnant within 6 months	☐	☐
3. Abnormal result on coagulation test, or platelet count ⩽ 50000 / L, or with any complications of hemorrhagic disease	☐	☐
4. Local skin lesions such as burns, eczema, ulcers, frostbite ulceration and other contraindications for acupuncture treatment	☐	☐
5. Patients with needle phobia	☐	☐
6. Could not follow or response to treatment instructions	☐	☐

If any of the above items is answered with "Yes", the patient could not be recruited in the trial.

Informed consent

Date of signing informed consent: __ __ (Day) __ __ (Month) __ __ __ __ (Year)

(Attach Allocation Card Here)

Baseline assessment

Day 0 (Baseline)

1. General information

1.1. Date of Birth: ☐☐ (Day) ☐☐(Month) ☐☐☐☐(Year)　Age: ☐☐

1.2. Gender: ☐Male ☐Female

1.3. Marital status: ☐Married ☐Single ☐Divorced ☐Widowed

1.4. Nationality: ☐Han ☐Other: _____

1.5. Height: ☐☐☐cm　Weight: ☐☐☐kg

1.6. Degree of education: ☐ no formal education ☐Primary school ☐Junior high school ☐Senior high school or technical secondary school ☐Junior college or bachelor degree ☐Master degree or above

1.7. Occupation: ☐Worker ☐Farmer ☐Student ☐ Politician ☐Professional ☐Retired ☐ Freelancer ☐Other: _____

1.8. Settlement: ☐Guangdong, China ☐Other: _____

2. Vital Signs

2.1. Body temperature☐☐.☐℃

2.2. Respiratory rate ☐☐ times/minute

2.3. Heart rate ☐☐☐ Beats/ minutes

2.4. Blood Pressure ☐☐☐ mmHg/ ☐☐☐ mmHg

3. History of allergy

☐No ☐Yes (If yes, please record the following details)

3.1. Allergic to medication _____

3.2. Allergic to food _____

3.3. Contact allergy _____

4. History of cancer

4.1. Tumor types: ☐ (1. Lung cancer 2. Liver cancer 3. Gastric cancer 4. Intestinal/colorectal cancer 5. Ovarian cancer 6. Breast cancer 7. Nasopharyngeal carcinoma 8. Other _____)

Date of initial diagnosis of tumor: ☐☐ (Day) ☐☐(Month) ☐☐☐☐(Year)

Primary site: _____

4.2. The current TNM staging: T☐ N☐ M☐

Clinical classification ☐: 0.0 Stage 1. Hidden Stage 2.Ia Stage 3.Ib Stage 4.IIa Stage 5.IIb Stage 6.IIIa Stage 7.IIIb Stage 8.IV Stage

Date of diagnosis: ☐☐ (Day) ☐☐(Month) ☐☐☐☐(Year)

4.3. The current anti-cancer treatment☐: 1. First-line program 2. Second-line program 3. Third-line and above programs

Evaluation of the effect of cancer treatment☐: 1. CR, complete response 2. PR, partial response 3. SD, stable disease 4. PD, progressive disease

5. Treatments for cancer

5.1. Surgery ☐No ☐Yes (If Yes, please provide details of treatment)

Name of surgery	Date of surgery	Purpose of surgery
	☐☐ (Day) ☐☐(Month) ☐☐☐☐(Year)	☐Palliative ☐Curative
	☐☐ (Day) ☐☐(Month) ☐☐☐☐(Year)	☐Palliative ☐Curative
	☐☐ (Day) ☐☐(Month) ☐☐☐☐(Year)	☐Palliative ☐Curative

5.2. Radiotherapy ☐No ☐Yes (If yes, please provide details)

Location of radiotherapy	Date of radiotherapy	Purpose of radiotherapy
	☐☐ (Day) ☐☐(Month) ☐☐☐☐(Year)	☐Assistive ☐Palliative ☐Curative
	☐☐ (Day) ☐☐(Month) ☐☐☐☐(Year)	☐Assistive ☐Palliative ☐Curative
	☐☐ (Day) ☐☐(Month) ☐☐☐☐(Year)	☐Assistive ☐Palliative ☐Curative

5.3. Chemotherapy ☐No ☐Yes (If yes, please provide details)

Starting date	End date	Treatment type: 1 adjuvant therapy 2 neoadjuvant therapy 3 advanced or diffuse lesions
☐☐ (Day) ☐☐(Month) ☐☐☐☐(Year)	☐☐ (Day) ☐☐(Month) ☐☐☐☐(Year)	☐1 ☐2 ☐3
☐☐ (Day) ☐☐(Month) ☐☐☐☐(Year)	☐☐ (Day) ☐☐(Month) ☐☐☐☐(Year)	☐1 ☐2 ☐3
☐☐ (Day) ☐☐(Month) ☐☐☐☐(Year)	☐☐ (Day) ☐☐(Month) ☐☐☐☐(Year)	☐1 ☐2 ☐3

6. Pain assessments

6.1. Score on Numerical rating scale ☐

- Verbal: “What number describes your pain from 0 (no pain) to 10 (worst pain you can imagine)?”
- Written: “Circle the number that describes your pain.”

0 1 2 3 4 5 6 7 8 9 10

No pain Worst pain you can imagine

Categorical scale:

“What word best describes your pain?”

None (0), Mild (1-3) , Moderate (4-6), or Severe (7-10)

6.2. Analgesic therapy ☐No ☐Yes (If yes, please provide details)

Name of analgesic	Usage and Dosage	Start date	Currently used?	If it is no longer used, please provide end date
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

6.3. Other therapy for pain control ☐No ☐Yes (If yes, please provide details)

Name of treatment	Usage and dosage	Start date	Currently used?	If it is no longer used, please provide end date
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

6.4. Frequency of breakthrough pain and rescue medication used in the past 24 hours

☐No ☐Yes (If yes, please provide details)

Onset time	Intensity (NRS)	Name, usage and dosage of rescue medication	Time administered
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)

7. Information from the perspective of Chinese medicine

7.1. Diagnostics in Chinese medicine

Tongue Diagnosis		
Body	Color ☐	1. Pale-red 2. Pale 3. Red 4. Crimson 5. Crimson and purple 6. Blue and purple 7. Pale and purple
	Shape ☐	1. Normal 2. Enlarged without tooth marks 3. Enlarged with tooth marks 4. Swollen 5. Small and thin tongue
	Texture ☐	1. Normal 2. Tough 3. Delicate
	Others	Speckles and Prickled ☐No ☐Yes Ecchymosis ☐No ☐Yes Cracked ☐No ☐Yes
Coating	Texture ☐	1. Thin coating 2. No coating 3. Little coating 4. Peeled coating 5. Thick coating 6. Greasy coating 7. Curd-like coating
	Color ☐	1. White 2. Yellow 3. Grayish black
	Moisture ☐	1. Moist 2. Slippery 3. Dry 4. Coarse
Sublingual veins ☐		1. Normal 2. Big cyanotic 3. Thin, short, pale

Pulse Diagnosis ☐ 0. Normal 1. Abnormal, please provide details ☐ (Multiple choice)
1. Floating pulse 2. Deep pulse 3. Slow pulse 4. Rapid pulse 5. Surging pulse 6. Thready pulse 7. Faint pulse 8. Scattered pulse 9. Deficient pulse 10. Excess pulse 11. Slippery pulse 12. Rough pulse 13. Long pulse 14. Short pulse 15. Wiry pulse 16. Hollow pulse 17. Tight pulse 18. Moderate pulse 19. Drum-skin pulse 20. Firm pulse 21. Weak pulse 22. Soggy pulse 23. Hidden pulse 24. Bouncing pulse 25. Hasty pulse 26. Knotted pulse 27. Intermittent pulse 28. Racing pulse

Other signs		
Sleep ☐		1. Normal 2. Difficult to fall asleep 3. Easy to wake up 4. Keeping eyes open overnight 5. Lethargy 6. Drowsy
Thirst ☐		1. Neither thirst nor desire for drinking water 2. Thirst with a desire to drink hot (warm) water 3. Thirst with a desire to drink cold water 3. Thirst without much drinking of water
Appetite ☐		1. Normal 2. Anorexia 3. Decline in appetite 4. Reduction of food intake 5. Polyphagia and frequent hunger 6. Hungry without a desire to eat
Taste in mouth ☐		1. Normal 2. Bland 3. Bitter 4. Sweet 5. Sour 6. Salty 7. Puckery 8. Sticky and greasy
Defecation	Frequency ☐	1. Normal 2. Constipation 3. Diarrhea 4. Chronic diarrhea 5. Diarrhea before dawn 6. Constipation and diarrhea alternately
	Quality ☐	1. Normal 2. Dry 3. Pulpy 4. Loose stool 5. Watery 6. Undigested food stuff in stools 7. At first dry and then loose stool 8. Alternate loose and dry stools
	hematochezia ☐	1. No 2. Distant part bleeding 3. Near or new blood 4. Mucous bloody
	Feeling of defecation ☐	1. Normal 2. Unsmooth defecation 3. Tenesmus 4. Burning sensation in anus 5. Prolonged and uncontrolled diarrhea 6. Dropping of the anus
Urination	Color ☐	1. Normal 2. Clear and profuse 3. Scanty deep yellow
	Frequency ☐	1. Normal 2. Frequent 3. Increased nocturia 4. Difficult in urination 5. Retention of urine
	Amount ☐	1. Normal 2. Increased 3. Decreased
	Feeling of urination ☐	1. Normal 2. Stranguria 3. Dribble of urine 4. Incontinence 5. Enuresis

7.2. Chinese medicine therapies? ☐No ☐Yes (If yes, please provide details)

Name of treatment	Usage and dosage	Start date	Currently used?	If it is no longer used, please provide end date
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐No ☐Yes	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐No ☐Yes	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐No ☐Yes	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐No ☐Yes	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐No ☐Yes	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐No ☐Yes	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

Treatment records

1. Drop-out：Did the participant drop out：

☐No;

☐Yes, please fill in the form “Summary of Trial Completion” on Page 39.

2. Medications：Did the participant take any medication during the period：

☐No;

☐Yes, please fill in the form “Records of Medications and Other Therapies” on Page 40.

3. Adverse events：Is there any adverse event in the treatment period：

☐No;

☐Yes, please fill in the form “Reports of Adverse Events” on Page 41.

Name of participant：＿＿＿＿　　Participant ID：＿＿＿＿

Acupuncture treatment records (only need to fill in for the treatment group)

Day 1 (1st Treatment)

Date: ☐☐ (Day) ☐☐(Month) ☐☐☐☐(Year)　Duration of the therapies: ☐☐:☐☐ - ☐☐:☐☐　Signature of the acupuncturist: _____

Acupuncture points (Please specify: L- Left, R- Right)	
Needle (diameter × length) (mm)	
Reason for acupuncture point selection	
Manipulation (Reinforcing and reducing, electro-acupuncture, or warming needle moxibustion, etc.)	
Management of accidents during the treatment (if applicable)	(Briefly describe the process and related treatment for adverse events here, and fill in the form "Reports of Adverse Events")
Note	

Name of participant：＿＿＿＿　　Participant ID：＿＿＿＿

Day 2 (2nd Treatment)

Date: □□ (Day) □□(Month) □□□□(Year)　Duration of the therapies: □□:□□ - □□:□□　Signature of the acupuncturist: _____

Acupuncture points (Please specify: L- Left, R- Right)	
Needle (diameter × length) (mm)	
Reason for acupuncture point selection	
Manipulation (Reinforcing and reducing, electro-acupuncture, or warming needle moxibustion, etc.)	
Management of accidents during the treatment (if applicable)	(Briefly describe the process and related treatment for adverse events here, and fill in the form "Reports of Adverse Events")
Note	

Day 4 (3rd Treatment)

Date: ☐☐ (Day) ☐☐(Month) ☐☐☐☐(Year) Duration of the therapies: ☐☐:☐☐ - ☐☐:☐☐ Signature of the acupuncturist: _____

Acupuncture points (Please specify: L- Left, R- Right)	
Needle (diameter × length) (mm)	
Reason for acupuncture point selection	
Manipulation (Reinforcing and reducing, electro-acupuncture, or warming needle moxibustion, etc.)	
Management of accidents during the treatment (if applicable)	(Briefly describe the process and related treatment for adverse events here, and fill in the form "Reports of Adverse Events")
Note	

Day 6 (4th Treatment)

Date: ☐☐ (Day) ☐☐(Month) ☐☐☐☐(Year) Duration of the therapies: ☐☐:☐☐ - ☐☐:☐☐ Signature of the acupuncturist: _____

Acupuncture points (Please specify: L- Left, R- Right)	
Needle (diameter × length) (mm)	
Reason for acupuncture point selection	
Manipulation (Reinforcing and reducing, electro-acupuncture, or warming needle moxibustion, etc.)	
Management of accidents during the treatment (if applicable)	(Briefly describe the process and related treatment for adverse events here, and fill in the form "Reports of Adverse Events")
Note	

Name of participant：__ __ __ __   Participant ID：__ __ __ __

Analgesic treatment records (need to fill in for both groups)

Day 1

Analgesic therapy ☐No ☐Yes (If yes, please provide details)

Name of analgesic	Usage and Dosage	Start date	Currently used?	If it is no longer used, please provide end date
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

Other therapy for pain control ☐No ☐Yes (If yes, please provide details)

Name of treatment	Usage and dosage	Start date	Currently used?	If it is no longer used, please provide end date
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

Frequency of breakthrough pain and rescue medication used in the past 24 hours ☐No ☐Yes (If yes, please provide details)

Onset time	Intensity (NRS)	Name, usage and dosage of rescue medication	Time administered
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)

Signature of investigator：__________________   Date：___________________

Day 2

Analgesic therapy ☐No ☐Yes (If yes, please provide details)

Name of analgesic	Usage and Dosage	Start date	Currently used?	If it is no longer used, please provide end date
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

Other therapy for pain control ☐No ☐Yes (If yes, please provide details)

Name of treatment	Usage and dosage	Start date	Currently used?	If it is no longer used, please provide end date
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

Frequency of breakthrough pain and rescue medication used in the past 24 hours ☐No ☐Yes (If yes, please provide details)

Onset time	Intensity (NRS)	Name, usage and dosage of rescue medication	Time administered
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)

Signature of investigator：__________________ Date：___________________

Day 3

Analgesic therapy ☐No ☐Yes (If yes, please provide details)

Name of analgesic	Usage and Dosage	Start date	Currently used?	If it is no longer used, please provide end date
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

Other therapy for pain control ☐No ☐Yes (If yes, please provide details)

Name of treatment	Usage and dosage	Start date	Currently used?	If it is no longer used, please provide end date
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

Frequency of breakthrough pain and rescue medication used in the past 24 hours ☐No ☐Yes (If yes, please provide details)

Onset time	Intensity (NRS)	Name, usage and dosage of rescue medication	Time administered
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)

Signature of investigator：__________________ Date：___________________

Name of participant：__ __ __ __ Participant ID：__ __ __ __

Day 4

Analgesic therapy ☐No ☐Yes (If yes, please provide details)

Name of analgesic	Usage and Dosage	Start date	Currently used?	If it is no longer used, please provide end date
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

Other therapy for pain control ☐No ☐Yes (If yes, please provide details)

Name of treatment	Usage and dosage	Start date	Currently used?	If it is no longer used, please provide end date
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

Frequency of breakthrough pain and rescue medication used in the past 24 hours ☐No ☐Yes (If yes, please provide details)

Onset time	Intensity (NRS)	Name, usage and dosage of rescue medication	Time administered
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)

Signature of investigator：__________________ Date：___________________

Name of participant：__ __ __ __ Participant ID：__ __ __ __

Day 5

Analgesic therapy ☐No ☐Yes (If yes, please provide details)

Name of analgesic	Usage and Dosage	Start date	Currently used?	If it is no longer used, please provide end date
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

Other therapy for pain control ☐No ☐Yes (If yes, please provide details)

Name of treatment	Usage and dosage	Start date	Currently used?	If it is no longer used, please provide end date
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

Frequency of breakthrough pain and rescue medication used in the past 24 hours ☐No ☐Yes (If yes, please provide details)

Onset time	Intensity (NRS)	Name, usage and dosage of rescue medication	Time administered
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)

Signature of investigator：__________________ Date：___________________

Name of participant： __ __ __ __   Participant ID： __ __ __ __

Day 6

Analgesic therapy ☐No ☐Yes (If yes, please provide details)

Name of analgesic	Usage and Dosage	Starting date	Currently used?	If it is no longer used, please provide end date
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

Other therapy for pain control ☐No ☐Yes (If yes, please provide details)

Name of treatment	Usage and dosage	Start date	Currently used?	If it is no longer used, please provide end date
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

Frequency of breakthrough pain and rescue medication used in the past 24 hours ☐No ☐Yes (If yes, please provide details)

Onset time	Intensity (NRS)	Name, usage and dosage of rescue medication	Time administered
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)

Signature of investigator： ___________________   Date： ___________________

Name of participant：__ __ __ __ Participant ID：__ __ __ __

Day 7

Analgesic therapy ☐No ☐Yes (If yes, please provide details)

Name of analgesic	Usage and Dosage	Start date	Currently used?	If it is no longer used, please provide end date
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

Other therapy for pain control ☐No ☐Yes (If yes, please provide details)

Name of treatment	Usage and dosage	Start date	Currently used?	If it is no longer used, please provide end date
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

Frequency of breakthrough pain and rescue medication used in the past 24 hours ☐No ☐Yes (If yes, please provide details)

Onset time	Intensity (NRS)	Name, usage and dosage of rescue medication	Time administered
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)

Signature of investigator：__________________ Date：___________________

Name of participant：＿＿＿＿　　Participant ID：＿＿＿＿

Pain assessment records

Opioid titration period

Day 1

Evaluation time ☐☐ (Hour) ☐☐(Minute)

Score on Numerical rating scale ☐

- Verbal: "What number describes your pain from 0 (no pain) to 10 (worst pain you can imagine)?"
- Written: "Circle the number that describes your pain."

0 1 2 3 4 5 6 7 8 9 10

No pain　　Worst pain you can imagine

Categorical scale:

"What word best describes your pain?"

None (0), Mild (1-3) , Moderate (4-6), or Severe (7-10)

Evaluation time ☐☐ (Hour) ☐☐(Minute)

Score on Numerical rating scale ☐

- Verbal: "What number describes your pain from 0 (no pain) to 10 (worst pain you can imagine)?"
- Written: "Circle the number that describes your pain."

0 1 2 3 4 5 6 7 8 9 10

No pain　　Worst pain you can imagine

Categorical scale:

"What word best describes your pain?"

None (0), Mild (1-3) , Moderate (4-6), or Severe (7-10)

Signature of investigator：＿＿＿＿＿＿＿＿　　Date：＿＿＿＿＿＿＿＿

Name of participant：＿＿＿＿　　Participant ID：＿＿＿＿

Day 2

Evaluation time ☐☐ (Hour) ☐☐(Minute)

Score on Numerical rating scale ☐

- Verbal: "What number describes your pain from 0 (no pain) to 10 (worst pain you can imagine)?"
- Written: "Circle the number that describes your pain."

0 1 2 3 4 5 6 7 8 9 10

No pain　　Worst pain you can imagine

Categorical scale:

"What word best describes your pain?"

None (0), Mild (1-3) , Moderate (4-6), or Severe (7-10)

Evaluation time ☐☐ (Hour) ☐☐(Minute)

Score on Numerical rating scale ☐

- Verbal: "What number describes your pain from 0 (no pain) to 10 (worst pain you can imagine)?"
- Written: "Circle the number that describes your pain."

0 1 2 3 4 5 6 7 8 9 10

No pain　　Worst pain you can imagine

Categorical scale:

"What word best describes your pain?"

None (0), Mild (1-3) , Moderate (4-6), or Severe (7-10)

Signature of investigator：＿＿＿＿＿＿＿＿　　Date：＿＿＿＿＿＿＿＿

Name of participant：＿＿＿＿　　Participant ID：＿＿＿＿

Goals of analgesia achieved

Day 3

Evaluation time ☐☐ (Hour) ☐☐(Minute)

Score on Numerical rating scale ☐

- Verbal: "What number describes your pain from 0 (no pain) to 10 (worst pain you can imagine)?"
- Written: "Circle the number that describes your pain."

0 1 2 3 4 5 6 7 8 9 10

No pain　　Worst pain you can imagine

Categorical scale:

"What word best describes your pain?"

None (0), Mild (1-3) , Moderate (4-6), or Severe (7-10)

Evaluation time ☐☐ (Hour) ☐☐(Minute)

Score on Numerical rating scale ☐

- Verbal: "What number describes your pain from 0 (no pain) to 10 (worst pain you can imagine)?"
- Written: "Circle the number that describes your pain."

0 1 2 3 4 5 6 7 8 9 10

No pain　　Worst pain you can imagine

Categorical scale:

"What word best describes your pain?"

None (0), Mild (1-3) , Moderate (4-6), or Severe (7-10)

Signature of investigator：＿＿＿＿＿＿＿＿　　Date：＿＿＿＿＿＿＿＿

Name of participant：＿＿＿＿　　Participant ID：＿＿＿＿

Day 4

Evaluation time ☐☐ (Hour) ☐☐(Minute)

Score on Numerical rating scale ☐

- Verbal: "What number describes your pain from 0 (no pain) to 10 (worst pain you can imagine)?"
- Written: "Circle the number that describes your pain."

0 1 2 3 4 5 6 7 8 9 10

No pain　　Worst pain you can imagine

Categorical scale:

"What word best describes your pain?"

None (0), Mild (1-3) , Moderate (4-6), or Severe (7-10)

Evaluation time ☐☐ (Hour) ☐☐(Minute)

Score on Numerical rating scale ☐

- Verbal: "What number describes your pain from 0 (no pain) to 10 (worst pain you can imagine)?"
- Written: "Circle the number that describes your pain."

0 1 2 3 4 5 6 7 8 9 10

No pain　　Worst pain you can imagine

Categorical scale:

"What word best describes your pain?"

None (0), Mild (1-3) , Moderate (4-6), or Severe (7-10)

Signature of investigator：＿＿＿＿＿＿＿＿　　Date：＿＿＿＿＿＿＿＿

Name of participant：＿＿＿＿　　Participant ID：＿＿＿＿

Day 5

Evaluation time ☐☐ (Hour) ☐☐(Minute)

Score on Numerical rating scale ☐

- Verbal: "What number describes your pain from 0 (no pain) to 10 (worst pain you can imagine)?"
- Written: "Circle the number that describes your pain."

0 1 2 3 4 5 6 7 8 9 10

No pain　　Worst pain you can imagine

Categorical scale:

"What word best describes your pain?"

None (0), Mild (1-3) , Moderate (4-6), or Severe (7-10)

Evaluation time ☐☐ (Hour) ☐☐(Minute)

Score on Numerical rating scale ☐

- Verbal: "What number describes your pain from 0 (no pain) to 10 (worst pain you can imagine)?"
- Written: "Circle the number that describes your pain."

0 1 2 3 4 5 6 7 8 9 10

No pain　　Worst pain you can imagine

Categorical scale:

"What word best describes your pain?"

None (0), Mild (1-3) , Moderate (4-6), or Severe (7-10)

Signature of investigator：＿＿＿＿＿＿＿＿　　Date：＿＿＿＿＿＿＿＿

Name of participant：＿＿＿＿　　Participant ID：＿＿＿＿

Day 6

Evaluation time ☐☐ (Hour) ☐☐(Minute)

Score on Numerical rating scale ☐

- Verbal: "What number describes your pain from 0 (no pain) to 10 (worst pain you can imagine)?"
- Written: "Circle the number that describes your pain."

0 1 2 3 4 5 6 7 8 9 10

No pain　　Worst pain you can imagine

Categorical scale:

"What word best describes your pain?"

None (0), Mild (1-3) , Moderate (4-6), or Severe (7-10)

Evaluation time ☐☐ (Hour) ☐☐(Minute)

Score on Numerical rating scale ☐

- Verbal: "What number describes your pain from 0 (no pain) to 10 (worst pain you can imagine)?"
- Written: "Circle the number that describes your pain."

0 1 2 3 4 5 6 7 8 9 10

No pain　　Worst pain you can imagine

Categorical scale:

"What word best describes your pain?"

None (0), Mild (1-3) , Moderate (4-6), or Severe (7-10)

Signature of investigator：＿＿＿＿＿＿＿＿　　Date：＿＿＿＿＿＿＿＿

Name of participant：＿＿＿＿　　Participant ID：＿＿＿＿

Day 7

Evaluation time ☐☐ (Hour) ☐☐(Minute)

Score on Numerical rating scale ☐

- Verbal: "What number describes your pain from 0 (no pain) to 10 (worst pain you can imagine)?"
- Written: "Circle the number that describes your pain."

0 1 2 3 4 5 6 7 8 9 10

No pain　　Worst pain you can imagine

Categorical scale:

"What word best describes your pain?"

None (0), Mild (1-3) , Moderate (4-6), or Severe (7-10)

Evaluation time ☐☐ (Hour) ☐☐(Minute)

Score on Numerical rating scale ☐

- Verbal: "What number describes your pain from 0 (no pain) to 10 (worst pain you can imagine)?"
- Written: "Circle the number that describes your pain."

0 1 2 3 4 5 6 7 8 9 10

No pain　　Worst pain you can imagine

Categorical scale:

"What word best describes your pain?"

None (0), Mild (1-3) , Moderate (4-6), or Severe (7-10)

Signature of investigator：＿＿＿＿＿＿＿＿　　Date：＿＿＿＿＿＿＿＿

Name of participant：＿＿＿＿　　Participant ID：＿＿＿＿

Diagnostics in Chinese medicine

Tongue Diagnosis		
Body	Color ☐	1. Pale-red 2. Pale 3. Red 4. Crimson 5. Crimson and purple 6. Blue and purple 7. Pale and purple
	Shape ☐	1. Normal 2. Enlarged without tooth marks 3. Enlarged with tooth marks 4. Swollen 5. Small and thin tongue
	Texture ☐	1. Normal 2. Tough 3. Delicate
	Others	Speckles and Prickled ☐No ☐Yes Ecchymosis ☐No ☐Yes Cracked ☐No ☐Yes
Coating	Texture ☐	1. Thin coating 2. No coating 3. Little coating 4. Peeled coating 5. Thick coating 6. Greasy coating 7. Curd-like coating
	Color ☐	1. White 2. Yellow 3. Grayish black
	Moisture ☐	1. Moist 2. Slippery 3. Dry 4. Coarse
Sublingual veins ☐		1. Normal 2. Big cyanotic 3. Thin, short, pale

Pulse Diagnosis ☐ 0. Normal 1. Abnormal, please provide details ☐ (Multiple choice)
1. Floating pulse 2. Deep pulse 3. Slow pulse 4. Rapid pulse 5. Surging pulse 6. Thready pulse 7. Faint pulse 8. Scattered pulse 9. Deficient pulse 10. Excess pulse 11. Slippery pulse 12. Rough pulse 13. Long pulse 14. Short pulse 15. Wiry pulse 16. Hollow pulse 17. Tight pulse 18. Moderate pulse 19. Drum-skin pulse 20. Firm pulse 21. Weak pulse 22. Soggy pulse 23. Hidden pulse 24. Bouncing pulse 25. Hasty pulse 26. Knotted pulse 27. Intermittent pulse 28. Racing pulse

Other signs		
Sleep ☐		1. Normal 2. Difficult to fall asleep 3. Easy to wake up 4. Keeping eyes open overnight 5. Lethargy 6. Drowsy
Thirst ☐		1. Neither thirst nor desire for drinking water 2. Thirst with a desire to drink hot (warm) water 3. Thirst with a desire to drink cold water 3. Thirst without much drinking of water
Appetite ☐		1. Normal 2. Anorexia 3. Declined appetite 4. Reduction of food intake 5. Polyphagia and frequent hunger 6. Hungry without a desire to eat
Taste in mouth ☐		1. Normal 2. Bland 3. Bitter 4. Sweet 5. Sour 6. Salty 7. Puckery 8. Sticky and greasy
Defecation	Frequency ☐	1. Normal 2. Constipation 3. Diarrhea 4. Chronic diarrhea 5. Diarrhea before dawn 6. Constipation and diarrhea alternately
	Quality ☐	1. Normal 2. Dry 3. Pulpy 4. Loose stool 5. Watery 6. Undigested food stuff in stools 7. At first dry and then loose stool 8. Alternate loose and dry stools
	hematochezia ☐	1. No 2. Distant part bleeding 3. Near or new blood 4. Mucous bloody
	Feeling of defecation ☐	1. Normal 2. Unsmooth defecation 3. Tenesmus 4. Burning sensation in anus 5. Prolonged and uncontrolled diarrhea 6. Dropping of the anus
Urination	Color ☐	1. Normal 2. Clear and profuse 3. Scanty deep yellow
	Frequency ☐	1. Normal 2. Frequent 3. Increased nocturia 4. Difficulty in urination 5. Retention of urine
	Amount ☐	1. Normal 2. Increased 3. Decreased
	Feeling of urination ☐	1. Normal 2. Stranguria 3. Dribble of urine 4. Incontinence 5. Enuresis

Fellow-up records

Day 8-21

Score of Numerical rating scale ☐

- Verbal: “What number describes your pain from 0 (no pain) to 10 (worst pain you can imagine)?”
- Written: “Circle the number that describes your pain.”

0 1 2 3 4 5 6 7 8 9 10

No pain Worst pain you can imagine

Categorical scale:

“What word best describes your pain?”

None (0), Mind (1-3) , Moderate (4-6), or Severe (7-10)

Analgesic therapy ☐No ☐Yes (If yes, please provide details)

Name of analgesic	Usage and Dosage	Starting date	Currently use?	If it is no longer used, please provide ending date
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

Other therapy for pain control ☐No ☐Yes (If yes, please provide details)

Name of treatment	Usage and dosage	Starting date	Currently use?	If it is no longer used, please provide ending date
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
		☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

Frequency of breakthrough pain and rescue medication used in the past 24 hours

☐No ☐Yes (If yes, please provide details)

Onset time	Intensity (NRS)	Name, usage and dosage of rescue medication	Time administered
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)
☐☐ (Hour) ☐☐(Minute)	☐		☐☐ (Hour) ☐☐(Minute)

Name of participant：＿＿＿＿　　Participant ID：＿＿＿＿

Summary of Trail Completion

1. Did the participant complete the whole trial, including every treatment session and follow-ups: ☐Yes ☐No (If no, please complete the following blanks)

2. Date of withdrawal/termination: _____

2.1 Withdrawal/termination was first raised by (Please tick only one option):

☐Investigator ☐Participant

☐Other: _____

2.2 Reason for withdrawal/termination (Please tick only one option):

☐Adverse events ☐No or unsatisfied effects ☐Lost to follow-up ☐ Violate to trial protocol

☐Others: _____

Follow-up observation or visits after withdrawal/ termination of adverse events (Please provide details of process and outcomes of the adverse events):

_____

_____

_____

_____

_____

Signature of investigator：_____　　Date：_____

Name of participant：__ __ __ __   Participant ID：__ __ __ __

Records of Medications and Other Therapies

Is there any medication or other therapy (apart from analgesic and acupuncture) used during trial: ☐No ☐Yes (If yes, please complete the form below)					
Name of medication or therapy	For what condition	Usage and dosage	Starting date	Currently use?	If it is no longer used, please provide ending date
			☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
			☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
			☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
			☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
			☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
			☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
			☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
			☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)
			☐☐ (D) ☐☐(M) ☐☐☐☐(Y)	☐Yes ☐No	☐☐ (D) ☐☐(M) ☐☐☐☐(Y)

Signature of investigator：__________________   Date：___________________

Name of participant：__ __ __ __ Participant ID：__ __ __ __

Reports of Adverse Events

Is there any adverse event：☐No ☐Yes (If yes, please fill in the form below)		
Please record the events in details, including symptoms, signs, time, related test results and correspondent treatment with medical terminology:		
Name/General description		
Start time	__ __ (Hour): __ __ (Minute); __ __ (Day), __ __ (Month), __ __ (Year)	__ __ (Hour): __ __ (Minute); __ __ (Day), __ __ (Month), __ __ (Year)
Ending time	__ __ (Hour): __ __ (Minute); __ __ (Day), __ __ (Month), __ __ (Year)	__ __ (Hour): __ __ (Minute); __ __ (Day), __ __ (Month), __ __ (Year)
Severity	☐Mild ☐Moderate ☐Severe	☐Mild ☐Moderate ☐Severe
Is there any correspondent treatment	☐No ☐Yes (If Yes, please tick the correspondent treatment) Electro-acupuncture：☐remain the same dose ☐increase dose ☐reduce dose ☐temporarily stop using electro-acupuncture ☐permanent stop using electro-acupuncture ☐not applicable ☐not known Using other medications or therapies：☐No ☐Yes, please record these treatment in the form "Records of Medications and Other therapies"	☐No ☐Yes (If Yes, please tick the correspondent treatment) Electro-acupuncture：☐remain the same dose ☐increase dose ☐reduce dose ☐temporarily stop using electro-acupuncture ☐permanent stop using electro-acupuncture ☐not applicable ☐not known Using other medications or therapies：☐No ☐Yes, please record these treatment in the form "Records of Medications and Other therapies"
Correlation to electro-acupuncture	☐Certain ☐Probably/Likely ☐Possible ☐Unlikely ☐Conditional/Unclassified ☐Unassessable	☐Certain ☐Probably/Likely ☐Possible ☐Unlikely ☐Conditional/Unclassified ☐Unassessable
Outcome	☐Death ☐Symptom continue ☐ Symptom relieved or disappeared ☐ Symptom relieved or disappeared but with sequela ☐Symptom improving ☐Not known	☐Death ☐Symptom continue ☐ Symptom relieved or disappeared ☐ Symptom relieved or disappeared but with sequela ☐Symptom improving ☐Not known
Withdrawal	☐No ☐Yes	☐No ☐Yes
Is it a severe adverse event	☐No ☐Yes (If yes, please tick the correspondent ones below) ☐ Lethal ☐Life-threatening ☐Require hospitalization or prolong hospitalization duration ☐Lead to apparent or permanent disability or loss of working ability ☐ Lead to other critical medical incident	☐No ☐Yes (If yes, please tick the correspondent ones below) ☐ Lethal ☐Life-threatening ☐Require hospitalization or prolong hospitalization duration ☐Lead to apparent or permanent disability or loss of working ability ☐ Lead to other critical medical incident

Notes：

1. Adverse events include abnormal test results that were normal at recruitment. And the changes could not be explained by the development of the condition.

2. If the adverse events persist, please do not fill in the "ending time".

3. Severity of adverse events：Mild: temperate symptom that has no impact on daily living and requires simple treatment or no treatment; moderate: discomfort symptom that has an impact on

daily living, but can be relieved with treatment and would not lead to severe or permanent harm patient; severe: seriously impact daily living or the development of spasticity, or requiring stronger or larger dose of treatment.

4. Please copy and attach the additional pages of "Reports of Adverse Events" if there are more than two adverse events reported.

Signature of investigator: _____ Date: _____