IRAS no: 307628

Early **R**ib **A**nalgesia with **SER**ratus: **ERASER** Trial

A Pragmatic Randomised Control Trial Evaluating the Clinical and Cost-Effectiveness of Serratus Anterior Plane Block with Catheter Insertion compared to Usual Care in Patients with Multiple Rib Fractures

90 DAY FOLLOW UP FORM

This trial uses eCRF only , all data should be entered onto **https://bctu-redcap.bham.ac.uk** This form illustrates data being collected for follow up.

Section 1 - PARTICIPANT DETAILS

Trial no: ☐☐☐☐

Partial date of birth: *e.g. Jan 2023* M M M Y Y Y Y

Site ID: ☐☐☐☐

Date of assessment: *e.g. 31Jan2017*
D D M M M Y Y Y Y

Status: *Select one*
◯ Alive (continue to next item) ◯ Deceased *(complete change of status form)*

Section 2 - ADVERSE EVENTS

Did the participant experience any protocol defined expected SAE's during their admission: ◯ No ◯ Yes - please provide expected SAE ID

Expected SAE ID:

Details of SAE:

Section 3 - Charleson Comorbidity Index

Myocardial infarction: *Select one*	◯ No	◯ Yes	◯ Unknown	
Congestive heart failure: *Select one*	◯ No	◯ Yes	◯ Unknown	
Cerebrovascular disease: *Select one*	◯ No	◯ Yes	◯ Unknown	
Dementia *Select one*	◯ No	◯ Yes	◯ Unknown	
COPD: *Select one*	◯ No	◯ Yes	◯ Unknown	
Connective tissue disease: *Select one*	◯ No	◯ Yes	◯ Unknown	
Peptic ulcer disease: *Select one*	◯ No	◯ Yes	◯ Unknown	
Liver disease: *Select one*	◯ None	◯ Mild	◯ Moderate to severe	◯ Unknown
Diabetes mellitus: *Select one*	◯ None	◯ Without end-organ damage	◯ With end-organ damage	◯ Unknown
Hemiplegia or paraplegia: *Select one*	◯ No	◯ Yes	◯ Unknown	
Chronic kidney disease: *Select one*	◯ None	◯ Mild	◯ Moderate to severe	◯ Unknown
Solid tumour: *Select one*	◯ None	◯ Localised	◯ Metastatic	◯ Unknown
Leukaemia: *Select one*	◯ No	◯ Yes	◯ Unknown	
Lymphoma: *Select one*	◯ No	◯ Yes	◯ Unknown	
AIDS: *Select one*	◯ No	◯ Yes	◯ Unknown	

Section 4 - USE OF HEALTH CARE RESOURCES

1. In the last 3 months, please tell us the number of times you have seen your family doctor or other health care professional who is attached to your doctor's practice for your rib problem?

	Number of times in GP surgery	Number of times at home
Your GP or another GP	_ _	_ _
Practice nurse	_ _	_ _
District nurse	_ _	_ _
Physiotherapist	_ _	_ _
Psychologist	_ _	_ _
Counsellor	_ _	_ _
Acupuncturist	_ _	_ _
Chiropractor	_ _	_ _
Other, please specify all:	_ _	_ _

2. In the last 3 months, please tell us the number of times you have seen a health care professional(s), either in an outpatient NHS service or outpatient private care facility for your rib problem?

	Number of times in the NHS	Number of times privately	Cost of private treatment
Doctor	_ _	_ _	£
Nurse	_ _	_ _	£
Physiotherapist	_ _	_ _	£
Psychologist	_ _	_ _	£
Acupuncturist	_ _	_ _	£
Chiropractor	_ _	_ _	£
Other, please specify all:	_ _	_ _	£

3. In the last 3 months, please tell us if you have you been prescribed any medicines (e.g. painkillers) to help your rib problem?

	Name(s) of medication	Number of prescriptions in the last 3 months
Conventional painkillers (e.g. paracetamol, co-codamol)		_ _
Opioids (e.g. Codeine, morphine, oxycodone, tramadol)		_ _
Nuropathic painkillers (amitriptyline, pregabalin, gabapentin)		_ _
Anti-inflammatory drugs (e.g. Ibuprofen, naproxen, diclofenac)		_ _
Other, please specify all:		_ _

4. In the last 3 months, please tell us if you have bought any medicine(s), supplements, equipment or devices over the counter, without a prescription, for your rib problem?

	Type of medicine, supplement, equipment or device	Number of times bought	Cost
A)		_ _	£
B)		_ _	£
C)		_ _	£
D)		_ _	£
E)		_ _	£

5. Please state in the last 3 months, if you have had any medical investigations (e.g. X-Ray or blood test) either in an outpatient NHS service or outpatient private care facility for your rib problem?

	Number of times in the NHS	Number of times privately	Cost of private treatment
X-ray	_ _	_ _	£
CT scan	_ _	_ _	£
Ultrasound	_ _	_ _	
MRI	_ _	_ _	£
Chest drain	_ _	_ _	£
Blood test	_ _	_ _	£
Other, please specify all:	_ _	_ _	£

6. In the last 3 months, have you stayed overnight as an inpatient in either an NHS service or private care facility (or both) for your rib problem?

	Number of days as an NHS	Number of days as a private patient	Cost of private treatment
A&E	__ __	__ __	£
Level 0 (General ward)	__ __	__ __	£
Level 1 (Acute)	__ __	__ __	
Level 2 (HDU)	__ __	__ __	£
Level 3 (ICU)	__ __	__ __	£
Other, please specify all:	__ __	__ __	£

Please continue to next section

Section 5 - EQ-5D-5L (INTERVIEWER ADMINISTERED)

First, I would like to ask you about MOBILITY. Would you say that:

1. You have no problems in walking about? ❑
2. You have slight problems in walking about? ❑
3. You have moderate problems in walking about? ❑
4. You have severe problems in walking about? ❑
5. You are unable to walk about? ❑

Next, I would like to ask you about SELF-CARE. Would you say that:

1. You have no problems washing or dressing yourself? ❑
2. You have slight problems washing or dressing yourself? ❑
3. You have moderate problems washing or dressing yourself? ❑
4. You have severe problems washing or dressing yourself? ❑
5. You are unable to wash or dress yourself? ❑

Next, I would like to ask you about USUAL ACTIVITIES, for example work, study, housework, family or leisure activities. Would you say that:

1. You have no problems doing your usual activities? ❑
2. You have slight problems doing your usual activities? ❑
3. You have moderate problems doing your usual activities? ❑
4. You have severe problems doing your usual activities? ❑
5. You are unable to do your usual activities? ❑

Next, I would like to ask you about PAIN OR DISCOMFORT. Would you say that:

1. You have no pain or discomfort? ❑
2. You have slight pain or discomfort? ❑
3. You have moderate pain or discomfort? ❑
4. You have severe pain or discomfort? ❑
5. You have extreme pain or discomfort? ❑

Finally, I would like to ask you about ANXIETY OR DEPRESSION. Would you say that:

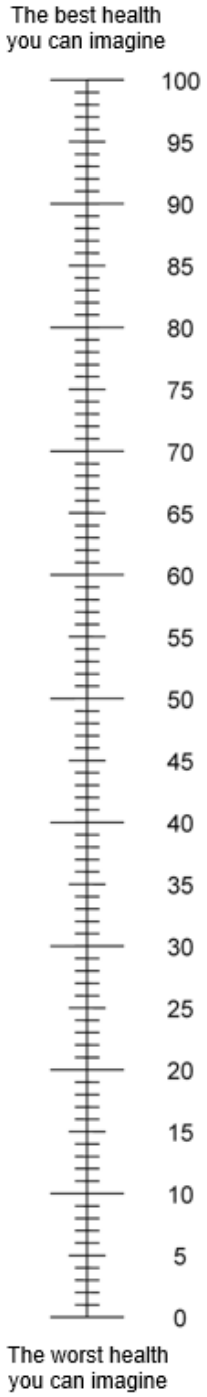
1. You are not anxious or depressed? ❑
2. You are slightly anxious or depressed? ❑
3. You are moderately anxious or depressed? ❑
4. You are severely anxious or depressed? ❑
5. You are extremely anxious or depressed? ❑

EQ-5D VAS

- **Now, I would like to ask you to say how good or bad your health is TODAY.**
- **I would like you to picture in your mind a vertical line that is numbered from 0 to 100.**
  (Note to interviewer: if interviewing face-to-face, please show the respondent the VAS line.)
- **100 at the top of the line means the <u>best</u> health you can imagine.**

  0 at the bottom of the line means the <u>worst</u> health you can imagine.
- **I would now like you to tell me the point on this line where you would put your health TODAY.**
  (Note to interviewer: mark the line at the point indicating the respondent's health today. Now, please write the number you marked on the line in the box below.)

THE RESPONDENT'S HEALTH TODAY = ☐



Section 6 - MRC DYSPNOEA SCALE (at 90 day follow up only)

Please ask the following questions about the degree of breathlessness:

Are you ever troubled by breathlessness except on strenuous exertion?	◯ No *(grade 1)* ◯ Yes *(go to next question)*
Are you short of breath when hurrying on the level or walking up a slight hill?	◯ No *(grade 1)* ◯ Yes *(go to next question)*
Do you have to walk slower than most people on the level? Do you have to stop after a mile or so (or after 1/4 hour) on the level at your own pace?	◯ No *(grade 2)* ◯ Yes to either *(go to next question)*
Do you have to stop for breath after walking about 100 yards (or after a few minutes) on the level?	◯ No *(grade 3)* ◯ Yes *(go to next question)*
Are you too breathless to leave the house, or breathless after undressing?	◯ No *(grade 4)* ◯ Yes *(grade 5)*

Used with the permission of the Medical Research Council. Ref: Fletcher CM . The clinical diagnosis of pulmonary emphysema—an experimental study. Proc R Soc Med 1952;45:577–584.

Section 7 - Short-Form McGill Pain Questionnaire-2 (SF-MPQ-2)

This questionnaire provides you with a list of words that describe some of the different qualities of pain and related symptoms. Please select the numbers that best describe the intensity of each of the pain and related symptoms you felt during the past 7 days. Use 0 if the word does not describe your pain or related symptoms.

1. Throbbing pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
2. Shooting pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
3. Stabbing pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
4. Sharp pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
5. Cramping pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
6. Gnawing pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
7. Hot-burning pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
8. Aching pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
9. Heavy pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
10. Tender	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
11. Splitting pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
12. Tiring-exhausting	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
13. Sickening	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
14. Fearful	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
15. Punishing-cruel	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
16. Electric-shock pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
17. Cold-freezing pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
18. Piercing	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
19. pain caused by light touch	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*

20. Itching	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
21. Tingling or 'pins and needles'	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
22. Numbness	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*

For any information on the use of the SF-MPQ-2, please contact Mapi Research Trust, Lyon, France. Internet: https://eprovide.mapi-trust.org

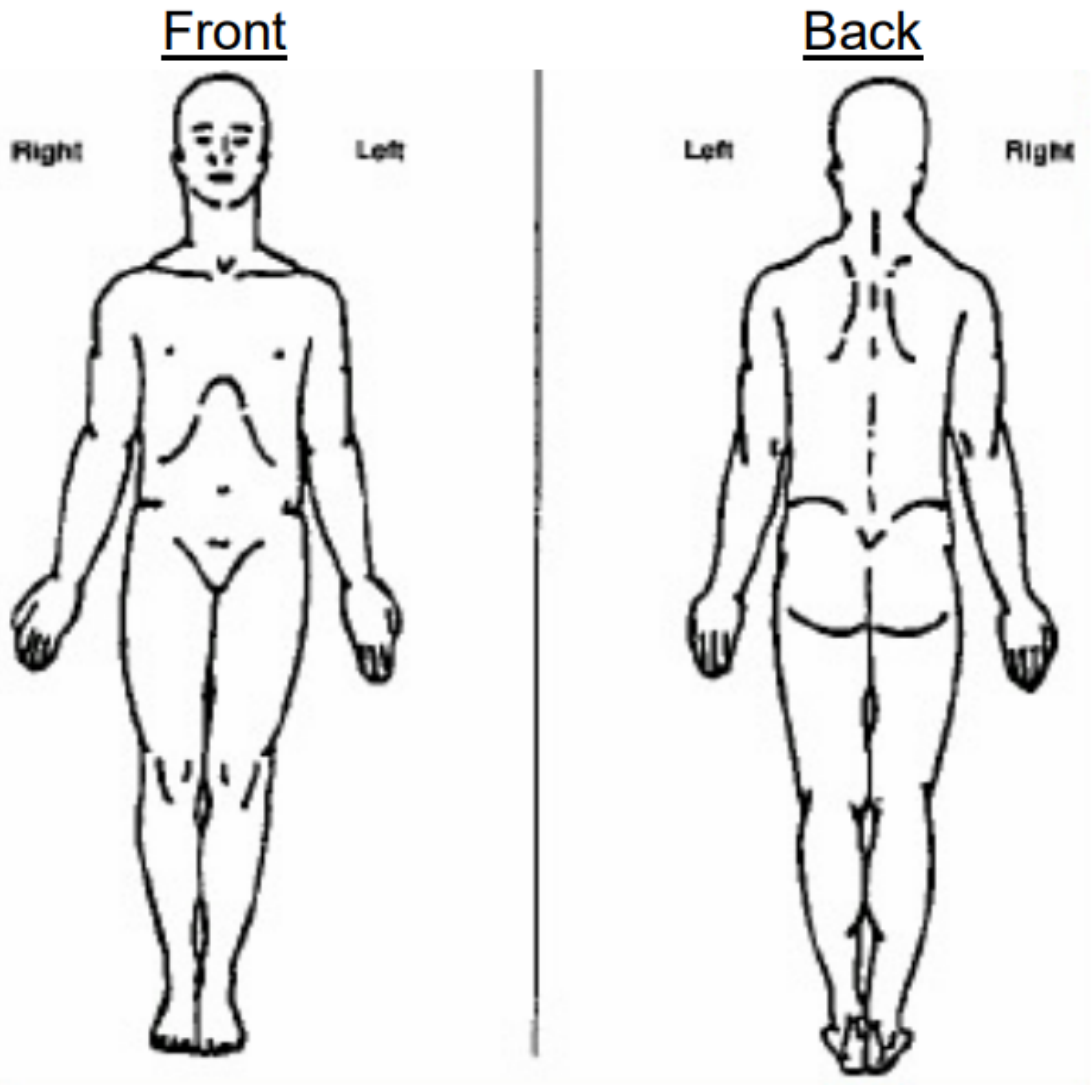
Please continue to next section

Section 8 - BRIEF PAIN INDEX (short form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

◯ Yes ◯ No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3) Please rate your pain by circling the one number that best describes your pain at its **WORST** in the past 24 hours

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

4. Please rate your pain by marking the box beside the number that best describes your pain at its **LEAST** in the last 24 hours.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

5. Please rate your pain by marking the box beside the number that best describes your pain on the **AVERAGE**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

6. Please rate your pain by marking the box beside the number that tells how much pain you have **RIGHT NOW**.

☐ 0 No Pain ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Pain As Bad As You Can Imagine

7. What treatments or medications are you receiving for your pain?

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please mark the box below the percentage that most shows how much relief you have received.

0% ☐ No Relief 10% ☐ 20% ☐ 30% ☐ 40% ☐ 50% ☐ 60% ☐ 70% ☐ 80% ☐ 90% ☐ 100% ☐ Complete Relief

9. Mark the box beside the number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity	☐ 0 Does Not Interfere	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 Completely Interferes
B. Mood	☐ 0 Does Not Interfere	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 Completely Interferes
C. Walking Ability	☐ 0 Does Not Interfere	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 Completely Interferes
D. Normal Work (includes both work outside the home and housework)	☐ 0 Does Not Interfere	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 Completely Interferes
E. Relations with other people	☐ 0 Does Not Interfere	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 Completely Interferes
F. Sleep	☐ 0 Does Not Interfere	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 Completely Interferes
G. Enjoyment of life	☐ 0 Does Not Interfere	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 Completely Interferes

Section 9 - FORM COMPLETED BY

This form should be completed by the Principal Investigator or researcher who has been delegated the duty of data collection on the Site Signature and Delegation Log.

Form completed by: *print name*	Signature:	Date of signature: D D M M M Y Y Y Y