

**Participant Pain Diary**

**Intraosseous Regional Administration of Diclofenac in Anterior Cruciate Ligament Reconstruction**

**Participant Study ID Number:\_\_\_\_\_\_\_\_\_\_\_\_**

**Date of study enrollment:\_\_\_\_\_\_\_\_\_\_\_\_**

**Date of operation:\_\_\_\_\_\_\_\_\_\_\_\_**

**Date of followup:**

* **2 Week:\_\_\_\_\_\_\_\_\_\_\_\_**
* **8 Week:\_\_\_\_\_\_\_\_\_\_\_\_**

**Investigator Signature Upon Completion:\_\_\_\_\_\_\_\_\_\_\_\_**

**Date of Study Completion:\_\_\_\_\_\_\_\_\_\_\_\_**

**Participant Pain Diary Instructions**

Welcome to your Pain Diary. This diary is an important part of the study, as it helps us understand your pain levels and how pain medications may be affecting your recovery. By recording this information regularly, you provide valuable insights that will help improve pain management for others in the future.

The data points captured in this diary and the instructions for filling them out are as follows:

**Recording Pain Levels (VAS Pain)**

Your current pain levels at rest and on movement will be reflected by your ‘visual analogue scale for pain’ (VAS Pain) score. This is a line that corresponds to a continuum of pain levels with the leftmost point of the line referring to ‘no pain’ and the rightmost point referring to the ‘worst possible pain’. You will put a mark on the line corresponding to the current level of pain you are in. Example is shown below.

No Pain

Worst Pain Possible

The times in which pain levels are to be recorded include hours 1, 2, and 3 following your surgery. If you do remain in hospital for any time longer than 3 hours following your surgery, please also record your pain levels every subsequent hour. Once at home, continue making pain level recordings at **8am and 6pm** everyday starting from the day after you have your surgery (post-op day 1) to the 7th day following your surgery (post-op day 7).

**Recording Pain Medications Used**

Please record ALL pain medications (i.e. morphine, paracetamol, tramadol, gabapentin etc) you use per day from the day after your surgery (post-op day 1) to the 7th day following your surgery (post-op day 7). An example on how to fill this out can be seen below. Alternatively, you can ask hospital staff for assistance.

|  |  |
| --- | --- |
| Medication Name | Total Dose (mg, tablets, etc.) |
| Morphine | 10mg |
| Paracetamol | 2 tablets |
|  |  |

**Recording Scores for Sleep**

These scores will represent how pain has interfered with your sleep over the past 24 hours. You will have to record a score on a scale from 0 to 10 (Numerical Rating Scale), from ‘does not interfere’ to ‘completely interferes’.

**Quality of Recovery (QoR-15) Survey**

You will be required to complete the QoR-15 survey the day following your operation. This measures the quality of recovery after anaesthesia and is an indicator of early postoperative health.

**Recording Adverse Events**

This section will be used by participants as well as researchers/study doctors. If an adverse event, that is any undesirable clinical event (such as a side effect of a medication, or technical procedure error etc), were to occur, patients or researchers/study doctors (where indicated) may record the details of the event in a table

**How to fill out the diary**  
Questionnaires will vary depending on the day. The diary has been ordered in such a way that you will only need to follow the day and complete the questions within that section/day. However, please remember to record any adverse events, should they arise, at the end of the diary.

**Post-Op Day 0**

1 Hour Post-Op:  
**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
  
2 Hours Post-Op:  
**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Post-Op Day 0 *Continued***  
3 Hours Post-Op:  
**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Post-Op Day 0 *Continued***

**Please fill out below if required:**

4 Hour Post-Op:  
**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
5 Hours Post-Op:  
**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Post-Op Day 0 *Continued***

5 Hours Post-Op:  
**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
  
6 Hours Post-Op:  
**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Post-Op Day 0 *Continued***  
7 Hour Post-Op:

**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
  
8 Hours Post-Op:

**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Post-Op Day 0 *Continued***  
  
9 Hours Post-Op:

**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Total Pain Relief Use - Post-Op Day 0

|  |  |
| --- | --- |
| Medication Name | Total Dose (mg, tablets, etc.) |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Post-Op Day 1**

Morning:

**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Evening:

**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

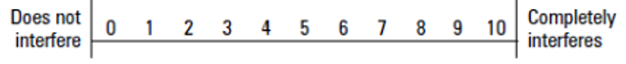
No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Post-Op Day 1 *Continued***

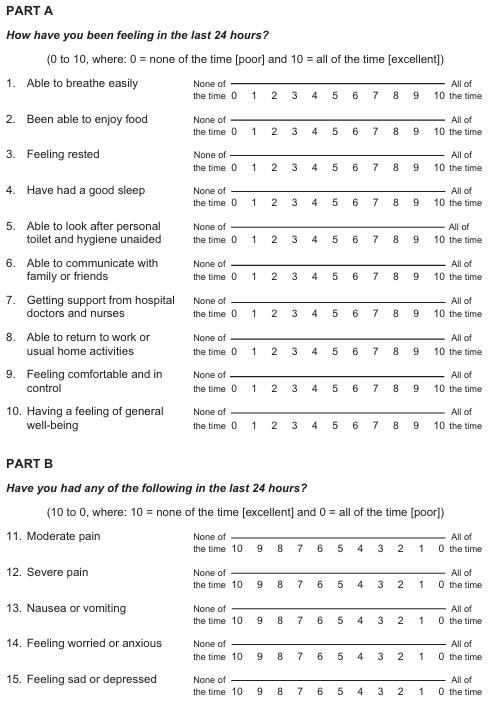
Does Pain interfere with your Sleep:



Total Pain Relief Use - Post-Op Day 1

|  |  |
| --- | --- |
| Medication Name | Total Dose (mg, tablets, etc.) |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Post-Op Day 1 *Continued***

****

*Investigator use only:*  
**QoR-15 total score:\_\_\_\_\_\_\_\_/150**

**Post-Op Day 2**

Morning:

**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Evening:

**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

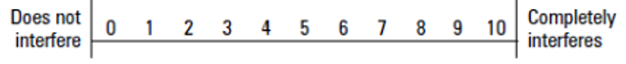
No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Post-Op Day 2 *Continued***

Does Pain interfere with your Sleep:



Total Pain Relief Use - Post-Op Day 2

|  |  |
| --- | --- |
| Medication Name | Total Dose (mg, tablets, etc.) |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Post-Op Day 3**

Morning:

**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Evening:

**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

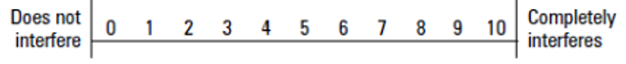
No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Post-Op Day 3 *Continued***

Does Pain interfere with your Sleep:



Total Pain Relief Use - Post-Op Day 3

|  |  |
| --- | --- |
| Medication Name | Total Dose (mg, tablets, etc.) |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Post-Op Day 4**

Morning:

**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Evening:

**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

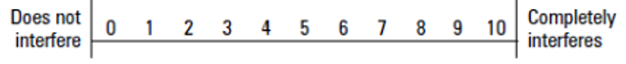
No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Post-Op Day 4 *Continued***

Does Pain interfere with your Sleep:



Total Pain Relief Use - Post-Op Day 4

|  |  |
| --- | --- |
| Medication Name | Total Dose (mg, tablets, etc.) |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Post-Op Day 5**

Morning:

**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Evening:

**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

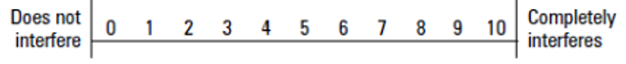
No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Post-Op Day 5 *Continued***

Does Pain interfere with your Sleep:



Total Pain Relief Use - Post-Op Day 5

|  |  |
| --- | --- |
| Medication Name | Total Dose (mg, tablets, etc.) |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Post-Op Day 6**

Morning:

**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Evening:

**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

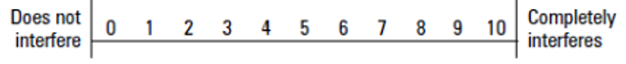
No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Post-Op Day 6 *Continued***

Does Pain interfere with your Sleep:



Total Pain Relief Use - Post-Op Day 6

|  |  |
| --- | --- |
| Medication Name | Total Dose (mg, tablets, etc.) |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Post-Op Day 7**

Morning:

**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Evening:

**Pain at Rest**

No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
  
**Pain at Mobilisation (e.g. moving in bed, getting in/out of bed)**

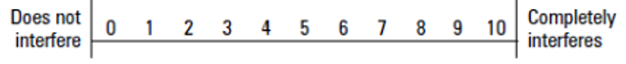
No Pain

Worst Pain Possible

*Investigator use only:*  
 VAS Pain (mm):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Post-Op Day 7 *Continued***

Does Pain interfere with your Sleep:



Total Pain Relief Use - Post-Op Day 7

|  |  |
| --- | --- |
| Medication Name | Total Dose (mg, tablets, etc.) |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Recording Adverse Events**

This section is for recording adverse events that occur throughout the duration of the study, whether it be side effects from medication, procedural complications, or other medical events etc. Researchers/study doctors will also be responsible for completing part of this section. We do encourage you to let nursing staff or your doctor know about any adverse events.

*For Participants and Study Doctors to complete:*

|  |  |  |
| --- | --- | --- |
| **Adverse Event/Occurrence** | **Description** | **Severity** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

*For Study Doctors to complete:*

|  |  |  |  |
| --- | --- | --- | --- |
| **Adverse Event/Occurrence (as per prev. table)** | **Relationship to Study Medication or Procedure** | **Treatment** | **Date of Resolution** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*This section is for study investigators to complete only:*

***Summary of Scores***

Table 1 - VAS Pain Scores Hours 1-9 Post-Op

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Hours Post-Op | Hour 1 | Hour 2 | Hour 3 | Hour 4 | Hour 5 | Hour 6 |
| VAS Pain at Rest (mm) |  |  |  |  |  |  |
| VAS Pain at Mobilising (mm) |  |  |  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Hours Post-Op | Hour 7 | Hour 8 | Hour 9 |
| VAS Pain at Rest (mm) |  |  |  |
| VAS Pain on Mobilising (mm) |  |  |  |

***Summary of Scores Continued***

Table 2 - VAS Pain Scores Days 1-7 Post-Op

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Day Post-Op | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 |
| Morning (8am) VAS Pain at Rest (mm) |  |  |  |  |  |  |  |
| Evening (6pm) VAS Pain at Rest (mm) |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Day Post-Op | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 |
| Morning (8am) VAS Pain on Mobilising (mm) |  |  |  |  |  |  |  |
| Evening (6pm) VAS Pain on Mobilising (mm) |  |  |  |  |  |  |  |

***Summary of Scores Continued***

Table 3 - Daily Total Opioid Use

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Day Post-Op | Day 0 | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 |
| Convert-ted MME |  |  |  |  |  |  |  |  |

Table 4 - Daily NRS for the Effect of Pain on Sleep

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Day Post-Op | Day 0 | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 |
| NRS Sleep |  |  |  |  |  |  |  |  |