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# Intensive monitoring of post-surgery pain in major ambulatory surgery

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 13/11/2025 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 01/12/2025 | Completed | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 01/12/2025 | Surgery | [X] Record updated in last year |

## Plain English summary of protocol

Background and study aims
Moderate to severe acute postoperative pain (APP) during part of the postoperative period is a barrier that hinders the central objective of perioperative medicine, which is to achieve an optimal postoperative recovery process. Despite advances in perioperative medicine, a large proportion of post-operative patients continue to suffer from moderate to severe APS during many of the days of their convalescence. This poor control of APS, in addition to causing suffering and exposing the patient to an increased risk of complications, could impair the quality of post-surgical recovery , according to some authors. It is of utmost interest in this field to corroborate whether the implementation of measures to better control the degree of acute pain are related to a better quality of post-surgical recovery. Currently, the growing trend to take into account the perspective of patients in their care has prompted the development of various patient-centred measurement tools that, among other aspects, assess the quality of post-surgical recovery. Several scales have been designed. The most widely used are the Quality of postoperative Recovery (QoR-40, QoR-9 and QoR-15 scales. The latter, with a range of 0 to 150, was developed to simplify assessment, especially in telephone follow-ups, and has a reliability similar to its predecessor, the QoR-40.

The study objectives are to demonstrate that the use of an intensive follow-up protocol improves the quality of postoperative recovery (QoR-15) two days after surgery compared to the use of the standard follow-up protocol.

Who can participate?
Adult patients aged 18 years and older scheduled for the surgeries: laparoscopic or open inguinal hernia repairs, laparoscopic cholecystectomies, haemorrhoid surgeries, knee arthroscopies, and shoulder arthroscopies.

What does the study involve?
Participants will be randomly allocated to two groups:
Intervention group (Intensive monitoring):
Participants receive the usual follow-up call the morning after surgery, plus daily phone calls to monitor pain until it is resolved.

Control group (Standard monitoring):
Participants receive only the routine follow-up call the morning after surgery.

What are the possible benefits and risks of participating?
The benefits could be better quality of recovery and better pain management, and there are no risks for the participants.

Where is the study run from?
Maresme Health Consortium, Spain.

When is the study starting and how long is it expected to run for?
February 2025 to August 2025.

Who is funding the study?
Maresme Health Consortium, Spain.

Who is the main contact?
Mr Sergio Vitale, svitale@csdm.cat

# Contact information

### Type(s)
Principal investigator

### Contact name
Mr Sergio Vitale

### Contact details
Carretera de Cirera, 230.
Mataró
Spain
08304
+34937417700
svitale@csdm.cat

### Type(s)
Scientific

### Contact name
Mrs Isabel Fabregas

### Contact details
Carretera de Cirera, 230.
Mataró
Spain
08304
+34937417700
mfabregas@csdm.cat

### Type(s)
Public

**Contact name**
Mrs Elisabet Palomera

**Contact details**
Carretera de Cirera, 230
Mataró
Spain
08304
+34937417700
epalomera@csdm.cat

# Additional identifiers

# Study information

**Scientific Title**
Intensive monitoring of post-surgery pain in major ambulatory surgery: viability study and results

**Study objectives**
Demonstrate that the use of the intensive follow-up protocol improves the quality of postoperative recovery (QoR-15) two days after surgery compared to the use of the standard follow-up protocol.

**Ethics approval required**
Ethics approval required

**Ethics approval(s)**
approved 24/02/2025, Comitè d'Ètica d'Investigació Clínica amb Medicaments de l'Hospital de Mataró, Consorci Sanitari del Maresme. (Carretera de Cirera, 230., Mataró, 08304, Spain; +34937417730; assajosclinics@csdm.cat), ref: CEIm 04/25

**Primary study design**
Interventional

**Allocation**
Randomized controlled trial

**Masking**
Blinded (masking used)

**Control**
Historical

**Assignment**
Parallel

**Purpose**
Health services research, Supportive care

### Study type(s)

### Health condition(s) or problem(s) studied
Hernioplasty
Cholecystectomy, laparoscopic
Haemorrhoidal surgery
knee arthroscopy
Shoulder arthroscopy

### Interventions
Participants were randomised using the REDCap platform to the following groups:
Intervention group: Intensive monitoring group. Routine follow-up (telephone call on the morning after surgery) and Intensive follow-up of acute post-surgery pain (telephone call every day since pain resolution).
Control group: Standard monitoring group. Routine follow-up (telephone call on the morning after surgery).

The duration of follow-up was 14 days, with Routine follow-up (telephone call on the morning after surgery) and Intensive follow-up of acute post-surgery pain (telephone call every day since pain resolution) for the Intervention group and Routine follow-up (telephone call on the morning after surgery) for the control group. Telephone follow-up was performed by some doctors and one nurse. The follow-up for the outcomes registry was at 48 hours post-surgical, on the 7th and 14th days.

### Intervention Type
Procedure/Surgery

### Primary outcome(s)
1. Quality of Recovery measured using the Quality of Postoperative Recovery (QoR-15) at baseline (pre-surgery) and 48 hours, 7 days and 14 days post-surgery

2. Pain Control measured using a Visual Analogic Scale (VAS) of pain at baseline (pre-surgery) and 48 hours, 7 days and 14 days post-surgery

3. Satisfaction of pain control measured using a 4-level Likert scale, according to the patient's criteria: dissatisfied, slightly dissatisfied, fairly satisfied, completely satisfied, at baseline (pre-surgery) and 48 hours, 7 days and 14 days post-surgery

4. Adherence to prescribed analgesic treatment measured using a 4-level Likert scale according to the patient's criteria: no adherence, low adherence, moderate adherence, and total adherence, at baseline (pre-surgery) and 48 hours, 7 days and 14 days post-surgery

### Key secondary outcome(s))

### Completion date
15/08/2025

# Eligibility

### Key inclusion criteria

1. Patients ≥ 18 years old
2. ASA I – III
3. Scheduled for the surgeries: Laparoscopic or open inguinal hernia repairs, Laparoscopic cholecystectomies, Haemorrhoid surgeries, Knee arthroscopies, Shoulder arthroscopies
4. Willingness to be contacted by telephone during the duration of the study
5. Informed written consent to participate in this study

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 years

### Upper age limit
100 years

### Sex
All

### Total final enrolment
280

### Key exclusion criteria
1. Lack of proficiency in Spanish
2. Undergoing study or follow-up for moderate to severe cognitive impairment
3. Pregnant or breastfeeding patients
4. Patients on major opioid medication
5. Patients with a history of dependence/abuse of alcohol or illicit drugs at present
6. Patients under active follow-up by the chronic pain unit

### Date of first enrolment
25/02/2025

### Date of final enrolment
05/08/2025

## Locations

### Countries of recruitment
Spain

### Study participating centre
**Universitary Mataró Hospital. Consorci Sanitari del Maresme.**
Mataró
Spain

# Sponsor information

**Organisation**
Maresme Health Consortium

**ROR**
https://ror.org/015jrdc82

# Funder(s)

**Funder type**

**Funder Name**
Consorci Sanitari del Maresme

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not expected to be made available