IC MD Protocol – Version 1 applicable as of 28 April 2022

PRI 2022 – HUS No. 8706

STUDY SUMMARY

Title of the clinical investigation

Evaluation of the feasibility of an expert patient decision-support system for optimizing the management of conditionally administered medications in a surgical ward

Short title

MORPHEE-2

Sponsor

Strasbourg University Hospitals

Principal Investigator

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HUS No.

8706

IDRCB No.

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Clinical Trial No.

NCT05707247

Rationale for the clinical investigation

The management of the numerous medications prescribed in connection with a surgical procedure represents a major challenge. Many new drugs are prescribed simultaneously, some of which are administered on an “as needed” basis, leading to a risk of suboptimal administration. The development of expert systems providing patient decision support represents a promising approach to improving perioperative medication management.

Primary Objective

To evaluate the feasibility of the INSAMED computerized decision-support tool regarding the administration of “as needed” medications after surgery.

Secondary Objectives

1. To evaluate the time to administration, according to current organizational practices, of medications prescribed on an “as needed” basis after surgery, in order to confirm the relevance of developing expert systems to improve current practice.
2. To assess patient satisfaction with the therapeutic response provided as part of routine care.
3. To assess patient satisfaction regarding the ease of use of the investigational device.
4. To assess the safety of the recommendations generated by the computerized tool.

Primary Evaluation Criterion

Rate of concordance between the recommendations provided by the INSAMED computerized tool and those established by healthcare professionals.

Recommendations generated by INSAMED will be collected through extraction of the usage history from the digital interface (commercial smartphone) hosting the expert system.

Recommendations established by a healthcare professional based on a best-practice algorithm will be determined after receipt of an activation message from the device: a research nurse (RN) will generate a recommendation based on the medical algorithm for symptom management, medical prescriptions, and patient interview, without consulting INSAMED.

Secondary Evaluation Criteria

1. **Time delay**, in minutes, between the patient’s request for a nurse according to usual practice (e.g., call bell) for pain, nausea/vomiting, or constipation, and administration of the therapeutic response.
   This delay will be recorded by the research nurse. The patient will simultaneously contact the ward nurse (call bell) and activate INSAMED, which will record the time of request.
2. **Patient satisfaction** with the therapeutic response provided by the ward nurse, measured using a visual analog scale from 0 to 100. Patient satisfaction will be analyzed according to whether there is concordance or discordance between the INSAMED recommendation and the nurse’s response.

3. **Patient satisfaction** regarding the ease of use of the INSAMED device, measured using a visual analog scale from 0 to 100.
4. **Grading of potential harm** associated with discrepancies between INSAMED recommendations and those established by the research nurse, according to the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) scale, adapted into three levels.

Study Design

Prospective, single-center pilot study.

Inclusion Criteria

- Male or female aged 18 years or older (no upper age limit)
- Undergoing surgery in a surgical department of Hautepierre Hospital, Strasbourg University Hospitals
- Able to read and understand French
- Neurosensorially capable of interacting with a tactile graphical interface
- Able to understand the objectives and risks of the research and provide dated and signed informed consent
- Affiliated with a social security health insurance scheme

Non-Inclusion Criteria

- Patients with neuropsychiatric or sensory disorders likely to interfere with use of the visual interface
- Inability to provide informed information (emergency situation, comprehension difficulties, etc.)
- Pregnant or breastfeeding women (self-reported)
- Patients under legal protection (guardianship, curatorship, or judicial safeguard)

Practical Conduct of the Study

Information and Inclusion Visit (V0)

- Anesthesia consultation or pre-anesthesia visit
- Signing of informed consent
- Training in the use of the INSAMED device

Visits V1 and V3: Day 0 +1 and Day 0 +2 (morning)

- Provision of the INSAMED device
- Reminder regarding its use

Vx: In case of pain, nausea/vomiting, or constipation

- Activation of INSAMED by the patient
- Call to the ward nurse for effective symptom management
- Patient answers INSAMED questions
- INSAMED: recommendation based on a programmed algorithm
- Visit by the research nurse (without access to INSAMED) 60 minutes after activation; the device sends an email alert upon activation
    - Recommendation based on a standard medical symptom treatment algorithm, medical prescriptions, and patient interview

The patient will be managed according to routine care recommendations, without consideration of INSAMED recommendations.

Visits V2 and V4: Day 0 +1 and Day 0 +2 (evening)

- Retrieval of the INSAMED device

Investigational Medical Device

The investigational medical device is a software prototype. It consists of a patient interface designed to assist patients with the administration of “as needed” medications in the postoperative period. The device is presented in the form of a smartphone with a tactile interface.

Participating patients are invited to activate the device when experiencing one of the following symptoms: pain, nausea/vomiting, or constipation. The device then asks the patient questions via the visual interface, to which the patient responds. The device subsequently issues a recommendation.

This recommendation is not communicated to the ward nurse responsible for patient care, who continues treatment according to routine care practices. The smartphone hosting the software is a CE-marked commercial smartphone manufactured by Samsung or Apple.

Authorized and/or Prohibited Medications/Treatments

Prescriptions will be made in accordance with routine practice. No treatment is prohibited.

Number of Subjects Required

30 subjects

The required number of subjects for this pilot study was set at 30 based on pragmatic feasibility considerations and in accordance with empirical rules described by Arain. Additionally, as data are repeated for each of the 30 subjects, the statistical power will be greater than that of a test conducted on 30 subjects without repeated measures.

If a patient never activates the device, an additional patient will be included until 30 patients have activated the device at least once. Therefore, the required number of subjects corresponds to the number of subjects who have used the device at least once, not the number of subjects enrolled, which is expected to be higher.

To achieve this objective, **60 patients are targeted for inclusion**.

Statistical Methods

Statistical analysis will include an initial descriptive phase (mean, median, standard deviation, and interquartile range for quantitative data; counts and percentages for qualitative variables).

Analysis of the primary endpoint will consist of evaluating concordance between the application's recommendation and that of the research nurse. As these are repeated binary data, concordance will not be assessed using a kappa coefficient, but rather through calculation of an intraclass correlation coefficient (ICC) derived from a mixed-effects logistic regression model with a random subject effect. Residual variance will be indirectly estimated using the methods described by Chakraborty et al.

The ICC will be reported with its 95% confidence interval, without formal hypothesis testing, as this is a pilot study.

Projected Timeline

- **Inclusion period duration:** 12 months
- **Participation duration per subject:** 2 days to a maximum of 2 months
- **Total study duration:** 14 months
- **Exclusion duration:** Not applicable

End of the research

The end of the research corresponds to the last visit of the last subject participating in the study.

Version 1.2 dated 20/12/2022, approved by the CPP Île-de-France II on 09/01/2023 and submitted to the ANSM on 13/01/2023