Implementation of a remote home monitoring program for patients with a mild acute pancreatitis - A multicenter feasibility study (INTERACT)

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To assess the feasibility of a novel care program in which patients with a predicted mild course of acute pancreatitis are discharged early with remote home monitoring.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Exocrine pancreas conditions
Study type	Interventional

Summary

ID

NL-OMON53197

Source
ToetsingOnline

Brief title
INTERACT

Condition

- Exocrine pancreas conditions

Synonym
Acute inflammation of the pancreas, acute pancreatitis

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Philips,Ziekenhuis Rijnstate;Arnhem;Jeroen

Bosch ziekenhuis;'s-Hertogenbosch en Isala;Zwolle.

Intervention

Keyword: Acute pancreatitis, Early discharge, Remote home monitoring

Outcome measures

Primary outcome

The main study objective is to assess the feasibility of the novel care program. Feasibility is determined by, patient satisfaction and actual use of the novel care program, for which the following parameters will be assessed:

Patient satisfaction:

- Satisfaction with overall care (from GE-ward admittance until discontinuation of remote home monitoring)
- Satisfaction with smartphone app
- Satisfaction with wearable sensor (Rijnstate)
- Intent to participate in the care program again

Actual use of the novel care program:

- Proportion of patients willing and able to participate
- Time between discharge decision and actual hospital discharge
- Duration of remote home monitoring
- Number of contacts between patients and healthcare professionals
- Number of additional laboratory tests
- Smartphone app functionality (generated notifications, time between notification and contact with VMC-nurse and questionnaire compliance)

- Wearable sensor functionality (missing data and accidental detachment)

(Rijnstate)

Secondary outcome

The secondary study objective is to describe clinical outcomes of patients in

the novel care program, for which the following parameters will be assessed:

- Utilization of analgesics and anti-emetics

- Pain scores

- Food tolerance

- Activity levels

- Time between GE ward admission and discharge decision

- Hospital readmissions within 30 days of hospital admission

- Emergency department (ED) revisits within 30 days of hospital admission

- Pancreatitis-related complications within 30 days of hospital admission

- Mortality within 30 days of hospital admission

Study description

Background summary

Acute pancreatitis is an inflammation of the pancreas which causes abdominal pain and is the most common gastro-intestinal reason for acute hospitalization in Western countries. Because care for patients with a mild acute pancreatitis is mostly supportive, providing this care in the home environment may be feasible with the use of remote monitoring. This might reduce the demand for hospital beds and allow patients to benefit from recovering in their home environment.

Study objective

To assess the feasibility of a novel care program in which patients with a predicted mild course of acute pancreatitis are discharged early with remote home monitoring.

Study design

A single center feasibility study

Intervention

After at least 48 hours of hospital admission, patients are discharged early with the use of remote home monitoring. At home, patients receive guidance for the management of pain, nutrition and pancreatitis-related complaints by a daily phone call from a nurse from the Virtual Monitoring Centre (VMC). The pancreatitis-related complaints, intake of fluids and food, pain and the use of analgesics are assessed using short questionnaires in a smartphone app. Core temperature is monitored using an ear thermometer and a wearable sensor measures heart rate, respiratory rate, posture and movement every 5 minutes (in case of inclusion at Rijnstate Hospital). Remote home monitoring will continue for at least 4 days.

Study burden and risks

During the patient's admission to the GE ward, where usual care is provided, patients are not exposed to additional tests or risks. However, following hospital discharge, the patient is required to provide multiple daily updates on their health status, which demands extra effort. Moreover, wearing the wearable sensor may cause minor discomfort. There might be a limited additional risk associated with the patient being at home, as they are further removed from immediate hospital care if necessary. Nevertheless, given the natural course of a mild acute pancreatitis and the study's stringent eligibility criteria, no medical emergencies related to early discharge are anticipated. Upon completion of remote home monitoring, the patient is requested to complete a satisfaction questionnaire, which will take approximately 10 minutes of their time. The outpatient appointment is part of usual care.

On the positive side, patients will have the opportunity to recover in their home environment, which is believed to have potential benefits for both their physical and mental well-being. Additionally, early discharge may contribute to reduced healthcare costs and alleviate the demand for hospital beds. This, in turn, enables healthcare professionals to focus their attention on patients in greater need of hospital care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Acute pancreatitis according to the revised Atlanta criteria for pancreatiti.
Which is at least 2 of the following 3 criteria:
- Abdominal pain consistent with acute pancreatitis
- Serum lipase >= 3x upper limit normal (> 159 U/l)
- Typical pancreatic abnormalities on imaging (ultrasound, CT or MRI)
• First episode of acute pancreatitis or a prior pancreatitis more than 3 months ago
• Age >=18 years, both men and women
• Able and willing to provide written informed consent in Dutch
• In possession of a working (smart)phone on which patient can be reached for the duration of participation (30 days)
• <=1 SIRS criteria:

* temperature < 36*C or > 38*C
* heart rate > 90/min
* respiratory rate >20/min
* leucocytes < 4x/109l or > 12x109/l
• Serum CRP <= 150 mg/l on day of discharge and with a decreasing trend in days before
• Pain score (NRS) <=6 with or without the use of pain medication
• Adequate intake of oral food and fluids (= >=2 small meals and >=1L fluids per day)
• Stable serum creatinine and Ringer's lactate infusion reduced to <1L/24 hours
• Independent in performing general daily life activities

Exclusion criteria

• Chronic pancreatitis according to M-ANNHEIM criteria.
• Acute cholangitis
• Endoscopic retrograde cholangiopancreatography within the first 24 hours of admission
• MEWS (Modified Early Warning Score) >=6 or in need of ICU admission
• Living in an institution (e.g. psychiatric ward or nursing home), or the absence of a household member capable of alerting the hospital in case of an emergency
• Known sensitivity to medical adhesives
• Known pregnancy
• Have one or more of the following comorbidities:
- Heart failure (NYHA class III or IV)
- COPD (Gold III-IV)
- Kidney disease (>G3b) and/or kidney replacement therapy
- Currently undergoing oncological treatment
- Use of immunosuppressants
- Dysregulated or poorly controlled insulin dependent diabetes
- Morbid obesity (BMI>35 kg/m2)
- Implantable Cardioverter Defibrillator (ICD) or Pacemaker

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-01-2024
Enrollment:	70
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	16-11-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-11-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT06178172
CCMO	NL84869.100.23