Remote home monitoring of patients with a predicted mild acute pancreatitis A safety study

Published: 16-01-2023
Last updated: 07-04-2024

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

Ethical review	Not approved
Status	Will not start
Health condition type	Exocrine pancreas conditions
Study type	Interventional

Summary

ID

NL-OMON51695

Source
ToetsingOnline

Brief title
REMAP

Condition

- Exocrine pancreas conditions

Synonym
inflammation of the pancreas, pancreatitis.

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Early discharge, Pancreatitis, Remote monitoring, Wearable sensor

Outcome measures

Primary outcome

The main endpoint of the study is the safety of early discharge with remote monitoring. Safety is defined by the incidence of unplanned hospital readmissions, the incidence of acute pancreatitis related complications and mortality, all within 30 days of hospital admission.

Secondary outcome

The secundary parameters of the study are length of stay in the hospital, duration of home monitoring, the amount of extra contacts between the nurse and patient, the amount of laboratory of imaging tests, adjustments in pain medication, patient satisfaction and overall costs.

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 a mild acute pancreatitis is supportive, early discharge of patients with a predicted mild course of acute pancreatitis might be safe with the use of remote home 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 safety of a novel care pathway in which patients, with a predicted mild course of acute pancreatitis, are discharged early with remote home monitoring.

Study design

A safety study.

Intervention

After at least 48 hours of hospital admission, patients are discharged early with the use of remote home monitoring. During home monitoring, heartrate, respiratory rate, posture and movement are monitored every 5 minutes for at least 4 days, using a wearable sensor. Core temperature is monitored using an ear thermometer. Patients are contacted once per day by a nurse from the Virtual Monitoring Centre (VMC) to assess pancreatitis related complaints, intake of fluids and food, pain and the use of analgesics. Patients are asked to provide information to the hospital using a smartphone app.

Study burden and risks

Patients are asked to wear a wearable sensor for the duration of the remote home monitoring, which might cause minor discomfort. In addition, the patient is asked to provide information about intake of fluids and food and possible complaints and have phone contact with the VMC-nurse once per day. Additional blood tests are only taken if necessary, which is expected to be less than the usual tests once per day during hospital admission. After discontinuation of the remote home monitoring, patients are asked to fill in a questionnaire to assess patient satisfaction. This novel care pathway might be associated with a small additional risk because patients are discharged early and are therefore not in close proximity of healthcare professionals in case of an emergency. However, early deterioration is expected to be detected by the remote monitoring of vital signs and the daily contact with the VMC-nurse. Furthermore, patients are able to contact the hospital 24 hours per day in case of an emergency and are provided with direct contact information of a healthcare professional to prevent delays.

Contacts

Public
Rijnstate Ziekenhuis

Wagnerlaan 55
Arnhem 6815 AD
NL
Scientific
Rijnstate Ziekenhuis

Wagnerlaan 55
Arnhem 6815 AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Have 2 out of 3 revised Atlanta criteria for pancreatitis:
- 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 possession of a working (smart)phone on which patient can be reached for the duration of participation (30 days).

Exclusion criteria

• Chronic pancreatitis according to M-ANNHEIM criteria.
• Signs of severe pancreatitis at the moment of admission to the GE ward:
- serum CRP > 150 mg/l
- more than one SIRS criteria:
* temperature < 36*C or > 38*C
* heart rate > 90/min
* respiratory rate >20/min
* leucocytes < 4x/109l or > 12x109/l
• MEWS (Modified Early Warning Score) >=6 or in need of ICU admission
• Living alone or in an institution (e.g. psychiatric ward or nursing home)

• 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:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	70
Type:	Anticipated

Ethics review

Not approved

Date:	16-01-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL81630.091.22