Implementation study of an evidence-based management algorithm for patients with chronic pancreatitis

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28232

Source
NTR

Brief title
COMBO

Health condition

Chronic pancreatitis

Sponsors and support

Primary sponsor: Erasmus MC, Department of Gastroenterology and Hepatology
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

There are two co-primary outcomes: quality of life assessed with a pancreatitis quality of life questionnaire and pain severity assessed with the Izbicki-pain score. Both will be measured longitudinally in all included patients.

Secondary outcome

1. Individual components of both co-primary outcomes
2. Process measure outcomes
3. Individual clinical outcomes
4. Participation at work
5. Healthcare resource utilization
6. Direct- and indirect costs

Study description

Background summary

Rationale: Chronic pancreatitis is associated with a markedly reduced life-expectancy and quality of life. In a recently performed study, current care for patients with chronic pancreatitis in the Netherlands proved not to be in accordance with the in 2017 published European guideline. This may indicate suboptimal care for these patients. Implementation of an evidence-based management algorithm to standardize care could improve this level of care, lower the complication rate and improve the quality of life for patients with chronic pancreatitis.

Objective: To assess whether standardized care through the implementation of an evidence-based management algorithm of interventions for patients with chronic pancreatitis results in an improvement in quality of life and reduction of pain severity as compared to current practice.

Study design: A nationwide stepped-wedge, cluster randomized controlled trial. All participating hospitals cross over from current practice to care according to the treatment algorithm. The sequence of crossing over is randomized. Study participants will be enrolled during the current practice phase and be followed longitudinally until the end of the study. In the end, this evidence-based management algorithm will be implemented in all participating hospitals.

Intervention: Evidence-based management algorithm

Comparison: Care for chronic pancreatitis patients according to current practice.

Endpoints: In this study, there are two co-primary outcomes: quality of life and pain severity. Both will be measured longitudinally in all included patients. Follow-up period will be a minimum of 12 months after start intervention.

Study objective

The hypothesis of this study is that implementation of an evidence-based management

algorithm to standardize care will improve the level of care, lower the complication rate and improve the quality of life for patients with chronic pancreatitis.

Study design

The patient follow-up will be completed 35 months after randomization to determine the order in which each cluster group will undergo the cross-over.

Intervention

Evidence-based management algorithm consisting of a combination of interventions, all considered as part of best practice, based on the recommendations of the United European Gastroenterology evidence-based guidelines for the diagnosis and therapy of chronic pancreatitis (2017) and an extensive systematic literature analysis.

Contacts

Public
Erasmus MC
Fleur de Rijk

088 320 7050
Scientific
Erasmus MC
Fleur de Rijk

088 320 7050

Eligibility criteria

Inclusion criteria

- An age ≥ 18 years
- A diagnosis of CP according to the M-ANNHEIM criteria
- Active treatment in one of the participating hospitals
- Provided written informed consent (IC)

Exclusion criteria

- Pregnancy

- End-stage diseases (< 6 months estimated survival) due to cancer, chronic obstructive pulmonary disease and/or congestive heart failure
- Suspected or established pancreatic malignancies
- Uncompensated cirrhosis
- Renal failure (GFR < 25 ml/min or who are on dialysis)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	120
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	23-04-2020
Application type:	First submission

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
NTR-new	NL8556
Other	MEC-U : W20.074

Study results