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

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28232

Bron
NTR

Verkorte titel
COMBO

Aandoening

Chronic pancreatitis

Ondersteuning

Primaire sponsor: Erasmus MC, Department of Gastroenterology and Hepatology
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Fleur de Rijk

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	23-04-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8556
Ander register	MEC-U : W20.074

Resultaten