Pancreatic Cyst Follow-up study

Gepubliceerd: 10-04-2014 Laatst bijgewerkt: 18-08-2022

To establish the yield of pancreatic cyst surveillance, based on the recently published European consensus statement, and to identify possible alternative, more (cost) effective, surveillance strategies.

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

Samenvatting

ID

NL-OMON27080

Bron
NTR

Verkorte titel
PACYFIC study

Aandoening

Pancreatic cysts
Follow-up
Pancreatic cystic neoplasms

Ondersteuning

Primaire sponsor: Erasmus University Medical Center in Rotterdam, The Netherlands
Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcomes are: the number of patients that reach an indication for surgical cyst resection and the number of patients diagnosed with a malignant cyst (either high-grade

dysplasia or carcinoma).

Toelichting onderzoek

Achtergrond van het onderzoek

The aim of the PACYFIC study is to establish the yield of regular pancreatic cyst surveillance, based on a recently published European Consensus statement, in terms of identified patients that require cyst resection, diagnosed malignancies, cyst evolution, and the perceived burden for participants. As a result, possible alternative, more (cost) effective, surveillance strategies may be identified. All patients with a pancreatic cyst, either newly or previously diagnosed, that require surveillance according to the opinion of
the treating physician, will be included. Surveillance will be based on the consensus statement, but at the discretion of the treating physician. Participating subjects will be asked to fill out online an questionnaire regarding the burden of surveillance after each follow-up visit.
The study will be implemented in several international centers in Europe.

Doel van het onderzoek

To establish the yield of pancreatic cyst surveillance, based on the recently published European consensus statement, and to identify possible alternative, more (cost) effective, surveillance strategies.

Onderzoeksopzet

The study will run for ten years.

Patients inclusion will be included from May 2014 until October 2023.

Follow-up will continue until April 2024.

The first analysis will be conducted in May 2017, after three years, to provide data for the MISCAN model.

Onderzoeksproduct en/of interventie

Cyst surveillance will be performed at the hospital of origin, based on the recommendations of the consensus statement. Patients will be followed every 6 to 12 months by imaging studies (preferably Magnetic Resonance Imaging (MRI/MRCP), with endoscopic ultrasonography (EUS) as an alternative) and determination of serum CA 19.9 levels. Both treating physicians and participating subjects will provide outcome data, by filling out (on-line) case record forms (CRF) and questionnaires. Cyst management will remain in the hands of the treating physician.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Individuals with a pancreatic cyst (either newly or previously diagnosed)

• Cyst surveillance is warranted, according to the treating physician

• Age >18

• Informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• History of chronic pancreatitis

• Suspected pseudocyst

• Suspected serous cystadenoma

• Von Hippel-Lindau disease

• Limited life expectancy (< 2 years)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2014
Aantal proefpersonen:	5000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-04-2014
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	NL4365
NTR-old	NTR4505
Ander register	METC Erasmus University Medical Center Rotterdam : MEC-2014-021

Resultaten