The prevalence of dyspepsia and IBS in patients with gallstones.

Gepubliceerd: 18-06-2018 Laatst bijgewerkt: 18-08-2022

The prevelance of FGID in patients with uncomplicated gallstones is higher compared to the general population

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

Samenvatting

ID

NL-OMON27555

Bron
Nationaal Trial Register

Verkorte titel
PERFECT-study

Aandoening

Gallstones, Cholecystolithiasis, Dyspepsia, Irritable Bowel Syndrome, Cholecystectomy.

Ondersteuning

Primaire sponsor: Radboud University Medical Center
Overige ondersteuning: Radboud University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The prevalence of Functional Dyspepsia (FD) and Irritable Bowel Syndrome (IBS) according to the ROME IV criteria.

Toelichting onderzoek

Achtergrond van het onderzoek

This study is a prospective, multicentre cohort study. In which we determine the prevalence of dyspepsia and IBS in patients with uncomplicated cholecystolithiasis;

All adult patients referred to the surgical outpatient clinic for gallstones will be considered for inclusion. Patients will all be recruited in The Netherlands.

They will be phoned by one of our researchers and asked if they want to participate in the study.

Before the first outpatient clinic visit (t=0), the patient characteristics, Rome IV Questionnaire, PAGI-SYM, Izbicki Pain Score, Gallstone Symptom List and Hospital Anxiety and Depression Scale will be taken.

After 6 months (t=6) the patients will receive the questionnaires again. In between some patients will be treated by means of a cholecystecomy and others won't get treatment (still observational).

After this, data management and statistical analysis will be carried out using IBM SPSS statistical software package version 22.0 (SPSS inc., Chicago, IL).

Doel van het onderzoek

The prevelance of FGID in patients with uncomplicated gallstones is higher compared to the general population

Onderzoeksopzet

t=0 months

-Patient characteristics:

- sex

- age

- BMI

- ethnic background

- smoking (packages per week)

- alcohol use (glasses per week)

- use of painkillers

- history or current treatment of: high blood pressure, high cholesterol or diabetes.

- other diseases

- history of operations or gastroscopy

- other medicine used besides painkillers

Gastrointestinal Disorders in Adults (R4DQ)

PAGI-SYM

Izbicki Pain Score (IPS)

Gallstone Symptom List (GSL)

Hospital Anxiety and Depression Scale (HADS)

t=6 months

Treatment, operation report, pathology, report

Gastrointestinal Disorders in Adults (R4DQ)

PAGI-SYM

Izbicki Pain Score (IPS)

Gallstone Symptom List (GSL)

Hospital Anxiety and Depression Scale (HADS)

Onderzoeksproduct en/of interventie

Questionnaires:

Rome IV Diagnostic Questionnaire for Functional Gastrointestinal Disorders in Adults (R4DQ)

PAGI-SYM

Izbicki Pain Score (IPS)

Gallstone Symptom List (GSL)

Hospital Anxiety and Depression Scale (HADS)

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 18 years of age or older, and

- with ultrasonically proven, uncomplicated cholecystolithiasis, and

- referred for surgical consultation

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- History of complicated cholelithiasis (i.e. choledocholithiasis, acute cholecystitis, biliary

pancreatitis or cholangitis)

- Current schizophrenia, memory deficiency, or any other disorder that predispose them to unreliable questionnaire responses;

- Mentally incompetent;

- Insufficient knowledge of the Dutch language;

- Known pregnancy

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2018
Aantal proefpersonen:	385
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-06-2018
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	NL7101
NTR-old	NTR7307
Ander register	Commissie Mensgebonden Onderzoek : 2017 3783

Resultaten