The prevalence of dyspepsia and IBS in patients with gallstones.

No registrations found.

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

Summary

ID

NL-OMON27555

Source
Nationaal Trial Register

Brief title
PERFECT-study

Health condition

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

Sponsors and support

Primary sponsor: Radboud University Medical Center
Source(s) of monetary or material Support: Radboud University Medical Center

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- What is the prevalence of gastroduodenal disorders and bowel disorders separately?

- What is the prevalence of overweight and obesity in the study population?

- Is the prevalence of patients with FGID that are scheduled for cholecystectomy different from those not scheduled?

- Which additional diagnostic tests are performed in patients not scheduled for surgery?

- Which therapeutic interventions are performed in patients not scheduled for surgery?

- Has symptom severity changed six months after the visit to the outpatient clinic and what is the influence of cholecystectomy on symptom severity?

- Is there a correlation between aspects (such as wall thickness) and motility of the gallbladder on ultrasonic and pathological examination, and the presence of FGID?

Study description

Background summary

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).

Study objective

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

general population

Study design

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)

Intervention

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)

Contacts

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Eligibility criteria

Inclusion criteria

- 18 years of age or older, and

- with ultrasonically proven, uncomplicated cholecystolithiasis, and

- referred for surgical consultation

Exclusion criteria

- 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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2018
Enrollment:	385
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-06-2018
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	NL7101
NTR-old	NTR7307
Other	Commissie Mensgebonden Onderzoek : 2017 3783

Study results