POLYP: a study for the treatment of gallbladder polyps

No registrations found.

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

Summary

ID

NL-OMON21733

Source
Nationaal Trial Register

Brief title
POLYP study

Health condition

Gallbladder polyps, transabdominal ultrasonography, cholecystectomy

Galblaaspoliepen, echografie, cholecystectomie

Sponsors and support

Primary sponsor: University medical center (Radboudumc)
Source(s) of monetary or material Support: Initiator

Intervention

Outcome measures

Primary outcome

- The number of patients reaching an indication for cholecystectomy during follow-up

- The number of patients with a histopathological diagnosis of neoplastic gallbladder polyps.

Secondary outcome

- Treatment outcome in terms of surgical complications, patient reported outcomes and the development of gallbladder cancer.

- Gallbladder polyp evolution in terms of growth, morphology, the development of worrisome features and symptomatology.

Study description

Background summary

Rationale: Gallbladder polyps can be divided into two pathological categories; pseudo polyps and true (neoplastic) polyps, the latter category harbouring malignant potential. Surgical intervention is only required for polyps at risk of malignant degeneration. Current guidelines advice surgical intervention based on size, growth rate and potential risk factors for malignancy. Cholecystectomy is advised for all polyps ≥ 10mm in size. However, this practise results in under- and overtreatment since size has been demonstrated to be an unreliable predictor of malignancy. The accuracy of current diagnostic methods is insufficient to detect and discriminate between different polyp entities. Improved pre-operative distinction between true and pseudo polyps could prevent morbidity and mortality as well as increase cost-efficacy of current treatment strategies for gallbladder polyps.

Objectives: To advance the diagnostic work-up and surveillance protocols for gallbladder polyps in order to improve the expediency of cholecystectomy for gallbladder polyps.

Study design: A multicentre, prospective cohort study with an expected duration of 5 years. The first analysis will be conducted after two years.

Study population: Patients >18 years of age diagnosed with gallbladder polyps by their treating physician requiring intervention or surveillance (based on current treatment guidelines) or with gallbladder polyps diagnosed post-operatively on histopathological analysis. Patients with a strong suspicion of malignancy will be excluded.

Intervention: Polyp surveillance and management will take place at the hospital of origin according to national guidelines and at the discretion of the treating physician. Diagnostic work-up consists of evaluation by at least one imaging study and polyp surveillance will be done by transabdominal ultrasonography (TAUS), following current guidelines. Questionnaires on symptoms and quality of life will be sent to the patients during follow-up and postoperatively.

Main study parameters/endpoints: The primary outcome parameters are the number of patients diagnosed with a gallbladder polyp reaching an indication for surgical intervention and the number of patients diagnosed with a neoplastic polyp on histopathology. Secondary outcome parameters are outcomes of patients with an indication for cholecystectomy(in terms of surgical complications and patient reported outcome measures) and gallbladder polyp evolution (in terms of growth, morphology and the development of worrisome features). Other outcome parameters are 1) clinical and imaging characteristics of patients with gallbladder polyps 2) risk factors for the malignant degeneration of gallbladder polyps 3) the diagnostic accuracy of TAUS in the classification of gallbladder polyps

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: No risks will be involved in the participation in this study. Both surveillance- and treatment protocols are in accordance with current guidelines. The only potential burden consists of filling in questionnaires on symptoms and quality of life during follow-up as well as post-operatively.

Study design

3 years.

Intervention

None.

Contacts

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Eligibility criteria

Inclusion criteria

- Suspected gallbladder polyp on TAUS, CT or MRI requiring surveillance or surgical treatment or patients with an incidental finding of gallbladder polyp on postoperative histopathological analysis after cholecystectomy for gallstone disease or cholecystitis.

- ≥18 years of age

- Informed consent

Exclusion criteria

- Inability to provide informed consent

- Insufficient control of the Dutch language to understand the patient information brochures / fill out questionnaires

Study design

Design

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

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-06-2018
Enrollment:	400
Type:	Unknown

Ethics review

Positive opinion

Date:	01-05-2018
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	NL7008
NTR-old	NTR7198
Other	CMO Arnhem-Nijmegen : 2018-4225

Study results