POLYP: a study for the treatment of gallbladder polyps

Gepubliceerd: 01-05-2018 Laatst bijgewerkt: 13-12-2022

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

Samenvatting

ID

NL-OMON21733

Bron
Nationaal Trial Register

Verkorte titel
POLYP study

Aandoening

Gallbladder polyps, transabdominal ultrasonography, cholecystectomy

Galblaaspoliepen, echografie, cholecystectomie

Ondersteuning

Primaire sponsor: University medical center (Radboudumc)
Overige ondersteuning: Initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- The number of patients reaching an indication for cholecystectomy during follow-up
- The number of patients with a histopathological diagnosis of neoplastic gallbladder

polyps.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Onderzoeksopzet

3 years.

Onderzoeksproduct en/of interventie

None.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Inability to provide informed consent

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

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: Anders

(Verwachte) startdatum:	01-06-2018
Aantal proefpersonen:	400
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	01-05-2018
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	NL7008
NTR-old	NTR7198
Ander register	CMO Arnhem-Nijmegen : 2018-4225

Resultaten