Diagnostic accuracy of MRI for gallbladder polyps; a prospective diagnostic pilot study

Published: 09-03-2016
Last updated: 19-04-2024

Primairy objective: To determine the diagnostic accuracy of MRI for the (differential) diagnosis of GB polyps and the differentiation between true and pseudo polyps in patients with suspected GB polyp(s) on previous imaging modality (TAUS) by using...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gallbladder disorders
Study type	Observational invasive

Summary

ID

NL-OMON42653

Source
ToetsingOnline

Brief title
DIAM-study

Condition

- Gallbladder disorders

Synonym
gallbladder polyp, polypoid lesion of the gallbladder

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: diagnosis, Galbladder, MRI, polyp

Outcome measures

Primary outcome

Test characteristics (sensitivity, specificity, predictive values, accuracy and number needed to treat (NNT)) of MRI (compared to histopathological analysis of the gallbladder) for the (differential) diagnosis of GB polyps and differentiation between true and pseudo polyps

Secondary outcome

Difference in test characteristics between MRI and TAUS for the (differential) diagnosis of GB polyps and the differentiation between true and pseudo polyps.

Study description

Background summary

Gallbladder (GB) polyps exist of two main pathological entities: true polyps (neoplastic) and pseudo polyps (nonneoplastic). Surgery is only needed for true polyps (potentially dysplastic or malignant). Based on current diagnostic procedures (mainly by transabdominal ultrasound) the differentiation between true and pseudo polyps is a dilemma due to inconsistent results. The decision for cholecystectomy is mainly based on size and growth of the polyp and concomitant suspicion of dysplastic or malignant degeneration.However postoperative many polyps with a diameter > 1cm prove to be pseudo polyps and some polyps < 1 cm have shown to be true polyps. Better differentiation between true and pseudo polyps and differential diagnosis by diagnostic modalities like MRI could prevent unnecessary surgeries and improve expediency and cost-effectiveness of cholecystectomy for GB polyps.

Study objective

Primairy objective: To determine the diagnostic accuracy of MRI for the (differential) diagnosis of GB polyps and the differentiation between true and pseudo polyps in patients with suspected GB polyp(s) on previous imaging

modality (TAUS) by using histopathological analysis of the gallbladder as reference standard.
Secundairy Objective: - To compare the diagnostic properties of MRI to those of TAUS and evaluate the position of MRI as second stage diagnostic tool in the diagnostic algorithm of patients suspected of GB polyps.
- In parallel to create a cohort of patients
with GB polyps to establish symptoms and characteristics of these patients and possible risk factors for GB polyps.

Study design

single centre prospective diagnostic pilot study. Patients from other hospitals may be referred to the Radboudumc for participation in this study. All information about the study will be given by the investigator of the Radboudumc and all study procedures will be performed at the Radboudumc.

Participating patients will be asked to come to the Radboudumc to undergo transabdominale ultrasound and MRI-scan. Both procedures will be performed and evaluated according standarised protocols by specialised radiologists. Radiologists are blinded for the result of the other imaging modality. Patients will additionaly be treated at the reffering center (mainly by cholecystectomy). Postoperative the results of the histopathological analysis will be requested to compare to the preoperative diagnosis of the transabdominal ultrasound and MRI-scan.

Study burden and risks

Included patients are already considered for cholecystectomy and will undergo two additional diagnostic tests to increase scientific knowledge on the diagnostics of GB polyps. Patients have to travel to the Radboudumc to undergo the diagnostic test and lay supine, mainly during the MRI, for about 45 minutes. Additional unknown medical problems might be found on MRI and will be reported to the treating physician. Transabdominal ultrasound and MRI have no adverse reactions of their own. Gadolinium contrast agent used during MRI can cause (mild) reactions in an extremely small percent of patients. Butylscopolamine administered during MRI may cause side-effects in a small proportion of patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Having proven GB polyp(s) (bij ultrasound or other imaging modality)
Being considered to undergo cholecystectomy
Aged 18 years or older
Providing informed consent

Exclusion criteria

Being pregnant
Having renal dysfunction (>=CKD 3)
Being unable to undergo MRI due to any reason (e.g claustrophobic, non MRI-compatible implants)
Known allergy or prior reaction to gadolinium-based contrast agent
Insufficient control of the Dutch language to understand the patient information/fill-out questionnaire
Unable to provide informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-05-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	09-03-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL55090.091.15