Prevalence of gastrointestinal disorders in the general population 50 to 75 years in the Ommoord municipality: videocapsule in the Rotterdam study

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What is the prevalence of gastro-intestinal disorders and which are the determinants?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON44830

Source
ToetsingOnline

Brief title
Videocapsule-ERGO

Condition

- Gastrointestinal conditions NEC
- Gastrointestinal neoplasms benign

Synonym
celiac disease, polyps, ulcers

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Given Imaging ltd.,KWF-

Kankerbestrijding;TKI-toeslag via LSH-Plaza/Zonmw;Given Imaging ltd.

Intervention

Keyword: epidemiology, prevalence, video capsule endoscopy

Outcome measures

Primary outcome

Prevalence of:

- Inflammation, ulcerations and erosions of the gastrointestinal tract,

including peptic ulcers

- Barrets esophagus

- Celiac disease

- Gastrointestinal bleeding

- Small bowel polyps

- Large bowel polyps

Secondary outcome

In this study, the entire digestive tract imaged. As a result, the research

provides information about the entire gastro-intestinal tract. These images are

relevant and of great value because they reveal information about prevalence of

diseases in the general asymptomatic population. ERGO hereby provides the

unique ability to relate this information to factors such as drug use, medical

history, and other determinants. In addition, the findings are compared with

the findings at endoscopy if subjects are referred for endoscopy.

Recently, an association was made between the microbiome and microRNA (miRNA)

and carcinogenesis. The gut microbiome consists of 100 trillion micro-organisms

in the gut and has an important immune, structural, metabolic and defence

function in the gut. MiRNAs are small non-coding regulatory RNAs with sizes of 20-24 nucleotides. Their function in the human genome consists of the regulation of gene expression. Both microbiome and miRNA could be involved in the carcinogenesis. To further explore the involvement in carcinogenesis, it is necessary to know the composition of the microbiome and miRNA in healthy individuals.

Study description

Background summary

The Rotterdam Elderly Study is a prospective cohort study in the Ommoord district in the city of Rotterdam, the Netherlands [Hofman et al., 1991]. Gastro intestinal diseases are common in the elderly population but accurate figures are unknown, partly because it is present without symptoms. For this reason, the true prevalence in the general population is unknown, mainly since most studies are performed in symptomatic populations. Video Capsule endoscopy (VCE) provides images of the entire gastrointestinal tract and can tehrefore be used to identify gastro-intestinal disorders.

Study objective

What is the prevalence of gastro-intestinal disorders and which are the determinants?

Study design

ERGO participants are invited by mail for this additional study by means of video capsule endoscopy. The study procedure mainly takes place at the participant's home, only ingestion of the capsule with application and activation of the sensor belt with data recorder takes place at the ERGO research center in Rotterdam.

Intervention

Participants are invited to videocapsule endoscopy (VCE) screening using the Pillcam colon 2L (Given Imaging ltd. Israel). Colon cleansing consists of a Senna tablet (Sennocol 185 mg; Meda Pharma BV, Amstelveen, The Netherlands) at bedtime 2 days before CCE. Subsequently all participants will start a liquid

diet at 13:00 the day before VCE and will receive 2 liter of polyethylene electrolyte glycol solution (Moviprep; Norgine, Amsterdam, The Netherlands) and 2 liter transparent fluid, split-dose. Booster during VCE procedure consists of additional 250ml Eziclen boost and an optional 250ml Eziclen boost, each followed by about 0.5 liter of clear liquids. The second administration is an optional booster, 3 hours after the first booster which participants will only be instructed to drink in case the capsule has not already been excreted. Procedure ends 10 hours after ingestion.

Participants are asked twice to complete a questionnaire about the expected and perceived burden; it will take 5-10 minutes to complete one questionnaire.

Participants are asked to perform a stool test (FIT)

Study burden and risks

Potential adverse events associated with the use of Pillcam colon 2L may include obstruction or retention of the capsule. Capsule retentions can be resolved by either laxative ingestion or removal of the capsule during colonoscopy or in very rare cases surgery. The procedure involves laxatives and prokinetic agents. See the SPC-texts of metoclopramide, moviprep, eziclen or bisacodyl for possible adverse events. It is made clear that participation is completely voluntary.

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

- 50-74 years
- participant Rotterdam study

Exclusion criteria

- Inability or refusal to provide informed consent.
- Persons with a severe or terminal disease with a life-expectancy of less than 5 years.
- An allergy or any other known contraindication to the medication used in this study
- Renal failure, eGFR <30 ml/min/1.73m2
- Congestive heart failure NYHA class III or IV
- Dysphagia or other swallowing disorder which makes it impossible to swallow the capsule.
- High risk of capsule retention: IBD, Personal history of gastrointestinal surgery other than uncomplicated procedures that would be unlikely to lead to bowel obstruction based on the clinical judgment of the investigator.
- Cardiac pacemakers or other implanted electro-medical equipment.
- An MRI scheduled within 14 days after ingestion of the capsule.
- Patients with diagnosed or suspected Congenital Long QT Syndrome
- Patients with concomitant use of drugs that prolong the QT interval

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-10-2017
Enrollment:	1000
Type:	Actual

Medical products/devices used

Generic name:	Pillcam Colon 2L videocapsule endoscopy
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	28-04-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-11-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-09-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL53967.078.15