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

Gepubliceerd: 23-12-2016 Laatst bijgewerkt: 18-08-2022

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26263

Bron
Nationaal Trial Register

Verkorte titel
Videocapsule_ERGO

Aandoening

Videocapsule endoscopy; Prevalence; Gastrointestinal disorders

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: - Health~Holland (previously known as Foundation LSH-TKI)
- Covidean AG
- Stichting Koningin Wilhelmina Fonds voor de Nederlands Kankerbestrijding (KWF): a health fund in The Netherlands
- Camerapil B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Prevalence of gastrointestinal disorders, visualized with colon capsule endoscopy

Toelichting onderzoek

Achtergrond van het onderzoek

The Rotterdam study (ERGO) is a prospective cohort study in the Ommoord district in the city of Rotterdam, The Netherlands.

Gastrointestinal 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 he entire gastrointestinal tract and can therefore be used to identify gastrointestinal disorders. Participants invited to video capsule endoscopy will be using the PillCam Colon 2 (Covidean AG). This capsule is 11,6 mm x 32.7 mm in size and each colon capsule has two imagers allowing nearly 360° coverage of the colon.

The study population consists of participants of the Rotterdam Study, aged between 50-74 years old. 1000 Persons will be included in the study. The primary aim of the study is the prevalence of inflammation, ulcerations and erosions of the gastrointestinal tract; Barrets esophagus; celiac disease; gastrointestinal bleeding, small bowel polyps and lager bowel polyps.

Further, in additional analysis, we will relate the prevalence with the information obtained from ERGO, such as factors as drug use, medical history and other determinants. In addition, the findings are compared with the findings at endoscopy of subjects are referred for endoscopy.

Onderzoeksopzet

n.a.

Onderzoeksproduct en/of interventie

Colon capsule endoscopy with corresponding bowel preparation

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Subject aged 50 untill 74 years old; Participation in the Rotterdam study

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Inability or refusal to provide informed consent; Persons with a severe or terminal disease with a life-expectancy of less than 5 years; Dysphagia or other swallowing disorder which makes it impossible to swallow the capsule; Renal failure, eGFR <30 ml/min/1.73m2; Subject has congestive heart failure (NYHA class 3 and 4); Subject has any allergy or other known contraindication to the medications used in the study; 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; Subject is expected to undergo MRI examination within14 days after ingestion of the capsule; Presumably or proven congenital long QT syndrome; Participants who use medication that give an extension of the QT- interval; subject has insulin dependent diabetes

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2017
Aantal proefpersonen:	1000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	23-12-2016
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	NL6174
NTR-old	NTR6321
Ander register	1.Medical Ethics Committee of Erasmus Medical Center; 2. Health~Holland : 1. MEC-2015-453; 2. 40-43100-98-011

Resultaten