Feasibility, Multi-center prospective study of Check-Cap's P1 Capsule System in Patients eligible for CRC screening

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To establish the safety and preliminary efficacy of Check-Cap*s P1 Capsule System in patients eligible for CRC screening

Ethical review	Approved WMO
Status	Pending
Health condition type	Benign neoplasms gastrointestinal
Study type	Observational invasive

Summary

ID

NL-OMON39301

Source
ToetsingOnline

Brief title
Check Cap-P1

Condition

- Benign neoplasms gastrointestinal
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
colorectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Check Cap Ltd
Source(s) of monetary or material Support: farmaceutical industry

Intervention

Keyword: check-cap, CRC-screening, feasibility

Outcome measures

Primary outcome

Primary Objective

To establish the safety and preliminary efficacy of Check-Cap*s P1 Capsule

System in patients eligible for CRC screening

Secondary outcome

Secondary Objective

• To evaluate the safety of the device in terms of total and segmental transit

time.

• To study the effect of the presence of polyps and variable colon dimensions

on these parameters.

• To monitor the functionality of the activation mechanism and of the scanning

circuitry (transmitter detectors).

• To collect data about the overall imaging of the colon internal surface

during the passage of the capsule

• Create an atlas of polyps images that enables comparison between images

acquired by different modalities - P1 capsule system,

Virtual Colonoscopy(if available as pre-study finding)

and colonoscopy

• To develop a correlation map between the imaging of the polyps by optical

colonoscopy vs. the images of same polyps by Check-

Cap*s P1 Capsule System vs. the imaging of same polyps by

Virtual Colonoscopy (in patients which were referred after positive

Virtual Colonoscopy examination)

• To estimate the total radiation exposure to each patient.

• To estimate the distribution of the contrast material within the colon.

• To compare the clinical findings with those of FOBT or FIT

Study description

Background summary

Check-Cap is an R&D stage company which is engaged in the development and commercialization of a miniaturized, ingestible disposable device for the screening of CRC market. The imaging is based on two modalities: a Compton backscattering Imaging and X-Ray technology
CRC -Colorectal cancer is the second leading cause of cancer death but is largely preventable. Current strategies to prevent colorectal cancer vary considerably with regard to effectiveness, up-front costs, risks, and invasiveness. Current levels of participation in colorectal cancer screening in the U.S. and Europe population are low. Both physician and patient attitudes contribute to low levels of screening uptake. New colorectal cancer tests are one mechanism to improve adherence.
Studies published in the early 1990s, showing that screening for colorectal cancer can reduce colorectal cancer-related mortality, led many organizations to recommend screening in asymptomatic, average-risk adults older than 50 years. Since then, however, national screening rates remain low in most countries. Several important studies published over the past four years have refined our understanding of existing screening tools and explored novel means of screening and prevention
In an attempt to reduce this cancer related death, legislation was passed in both the US and Germany in 2002, which establishes by law, reimbursement for screening colonoscopy in the population 50 years and older in the US, and 55 and older in Germany. This has increased the potential number of screening colonoscopies in these 2 countries alone to 15 million colonoscopies a year
Screening of the colon is performed by various modalities: FOBT, FIT, Sigmoidoscopy, endoscopic colonoscopy and virtual colonoscopy. These tests are invasive and require as well the cleansing of the colon. Most patients object the rigorous preparation required for cleansing of the colon. It is regarded as one of the main objections of patients to comply with the screening guidelines. The only way to bridge the gap between the number of colonoscopies presently performed and the potential market, is by way of a technological

breakthrough that will replace the cumbersome flexible colonoscope presently used for screening colonoscopy. Check-Cap Ltd believes that the device which it is developing may be just the answer needed to solve this public health issue.
1.1. Technology
The proposed device is designed to be ingested without any cleansing of the colon and will travel through the GI tract naturally while the patient continues eating normally. The technology of the P1 Capsule System is based on a low dose radioactive [RA] sealed source embedded in the capsule which radiates through a collimator to all directions. The capsule*s outer surface is covered by detectors which are designed to count the backscattered particles in a gamma energy spectrum. The capsule is designed to start scanning once it reaches the ceacum and the radiation is emitted only when the capsule is propagating along the colon during contraction of the walls. While stationary (which is most of the time) the capsule is set at an idle mode and the RA radiation is blocked by the collimator. The transit time of the capsule in the colon might vary from 24-100 hours, depending the typical bowel activity of the patient.

More details on the technology, capsule design, its structure and operation are presented in App. IIX

Check-Cap*s P1 Capsule System is an innovative disposable medical device that will enable a patient friendly, painless, private and accurate procedure for colorectal cancer screening.
For the screening procedure, the patient swallows a capsule and can then go about his or her normal daily routine. The capsule travels painlessly through the gastrointestinal tract, seeking polyps, the precursors of colorectal cancer. In order to increase the contrast of the colon*s walls and to differentiate them from their content, it is essential to increase the stool*s contrast by ingesting radio-opaque material. It is a standard procedure using approved Iodine based liquids (Telebrix or Gastrographine) or Barium sulphate Tagitol) at the discretion of the hospital similar to the preparation to abdominal CT.

During the passage of the capsule in the gastrointestinal tract, it transmits information to a worn recorder. After the capsule is expelled, the data from the recorder is downloaded to an acquisition workstation. Later, the data is transferred to a processing workstation where dedicated software visualizes and analyses the data. At the end of the procedure and after a colonoscopy, the patient will proceed following the standard procedure.

Study objective

To establish the safety and preliminary efficacy of Check-Cap*s P1 Capsule

System in patients eligible for CRC screening

Study design

Study design -
In order to get statistically significant results, patients will be recruited among those who were diagnosed with significant polyps by Virtual Colonoscopy (or diagnostic colonoscopy).
According to the definition in the literature of Virtual Colonoscopy studies - *significant* polyp, relates to polyps size of 10+ mm. Such population enrichment will introduce many more polyps into the study as compared to ~25% incidence of polyps in normal population and only 6-10% of significant ones (10 mm and up).
According to clinical guidelines, patients diagnosed with polyps using Virtual Colonoscopy are referred to polypectomy. In the proposed protocol, eligible patients will be evaluated by the P1 Capsule System and by FOBT before the therapeutic Colonoscopy procedure

Study burden and risks

• Colon perforation which lead to contamination of the abdominal cavity
• Retention of capsule for extended periods (>300 hours) while patient is not constipated
• Significant abdominal pain that requires medical attention.

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

- Male of female between 50 and 75 years of age
- Patients which are generally healthy
-Patients who are ready to undergo the capsule monitoring procedure and FOBT (or FIT) and the follow up colonoscopy examination
- Have a significant clinical finding(s) in prior colon examination with suspected colon polyp: Virtual Colonoscopy or diagnostic colonoscopy. This criteria will apply to a cohort of at least 25 patients out of the total population
- Sign informed consent.

Exclusion criteria

Patients with known GI related symptoms, complains or GI diseases such as:
- Crohn's disease
-Colitis
-IBD
-Chronic constipation
- Mega colon
-Strictures in the GI tract
- patients with cancer or other life threatening diseases or conditions
Pregnant women (to be verified by test in case of doubt)
•Patients who underwent any abdominal surgery
•Patients who underwent any endoscopic examination showing pathology (except polyps)
•Patients with cardiac pacer or any other implanted or external portable medical device (i.e. infusion pumps)
•Bed-ridden or sedentary patients
•Morbid Obesity (BMI > 40)
•Patients who are unable to undergo the bowel preparation necessary for optical colonoscopy (based on previous attempts or self declaration)
•Patients who are contraindicated from performing colon cleansing (bowel prep.)
•Drug abuse or alcoholism
•Patients under custodial care

•Participation in current clinical study or clinical study within 30 days prior to the procedure

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2013
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	19-08-2013
Application type:	First submission
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	NL34784.078.10