Remotely controlled, small intestinal release of 99mTcpertechnetate using an ingestible electronic device: the IntelliCap

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

Summary

ID

NL-OMON34038

Source
ToetsingOnline

Brief title
small intestinal 99mTc release and IntelliCap

Condition

- Other condition
- Gastrointestinal conditions NEC

Synonym
release of substances directly in the small intestine in healthy volunteers

Health condition

small bowel disorders

Research involving
Human

Sponsors and support

Primary sponsor: Philips Electronics Nederland B.V.
Source(s) of monetary or material Support: Philips Electronics Nederland B.V.

Intervention

Keyword: human, ingestible electonic device, radionuclides, small intestine

Outcome measures

Primary outcome

• Correlation of nuclear imaging data with environmental data (pH, temperature) generated by the IntelliCap system with respect to anatomical location.

• Nuclear imaging visualizing the release of 99mTc-pertechnetate in the small intestine

• Functionality of the IntelliCap (pH/temperature sensors and fidelity of communication between IntelliCap, portable unit, and control center) in the human body.

Secondary outcome

• Nuclear imaging visualizing the distribution profile of 99mTc-pertechnetate released in the small intestine

• Nuclear imaging visualizing distribution of released 99mTc-pertechnetate within the gastrointestinal tract and in relation to the IntelliCap

• Number and nature of adverse events

Study description

Background summary

Miniaturization of medical devices of which the functionality is completely controlled by microelectronics creates new possibilities for minimally invasive medical and clinical procedures. The investigational Philips IntelliCap system consists of a swallowable electronic device (capsule shaped, 26 mm long and 11 mm in diameter), capable of carrying about 300 microliter of liquid payload and ancillary equipment for real time recording of data. The IntelliCap capsule has two sensors (pH and temperature) that are used to determine the position of the device in the GI tract (e.g. low pH in stomach, rise in pH passage through pylorus, drop in pH passage through ileocecal valve). Propelled by natural peristalsis along the gastrointestinal tract, it records data (pH and temperature) from its immediate environment. Based on this information the operator may start dispensing a payload at a defined anatomical location by triggering the IntelliCap remotely. The IntelliCap system will be primarily used to conduct pre-clinical as well as clinical studies to study bioavailability and other pharmacokinetic parameters of different drug formulations, released at specified anatomical locations with customized release profiles, to guide further pharmaceutical formulation and dosage form development. Future applications may also comprise therapeutic applications like e.g. controlled intraluminal drug delivery in patients with inflammatory bowel disease or gastrointestinal cancer.

Study objective

The goal of the current study is to investigate the correlation of IntelliCap generated environmental information (gastrointestinal pH and temperature) with an established nuclear imaging technique. In addition, the functionality of the IntelliCap releasing a payload in the small intestine will be assessed. For this purpose, the IntelliCap will be loaded with 99mTc-pertechnetate, a commonly used agent in nuclear medicine imaging to visualize its position as well as the release and distribution of 99mTc-pertechnetate within the gastrointestinal tract. These data are required to assess the functional reliability of the IntelliCap system in terms of real time measuring of environmental information to determine its anatomical location as well as payload release at a defined anatomical location in the gastrointestinal tract in man. The present study will be performed in healthy volunteers.

Study design

Uncontrolled, open label study

Study burden and risks

The study requires ingestion of the IntelliCap, an electronic, medical device of 26*11 mm after fasting overnight. Subjects will be asked to wear a carrying

strap with a data recorder and relay unit (portable unit) until excretion of the IntelliCap. Short interruptions (e.g. taking a shower) are allowed. During night time, the portable unit might be taken off, but needs to be kept as close as possible to the body. Volunteers need to come to the study center for a screening visit for assessment of eligibility. A second visit to the clinical center will comprise ingestion of the IntelliCap in the morning of Day 1 followed by staying at the study center for approximately 8 hours. The end of study visit (Day 2) will be conducted the following day (about 24 hours after ingestion of the IntelliCap). After ingestion of the IntelliCap subjects will be asked to remain fasted until the completion of the dynamic imaging procedures after which they*ll be offered a sandwich and a soft drink. Approximately 4 hours after the ingestion of the IntelliCap subjects will be allowed normal food intake. Subjects are required to undergo both static (up to approximately 8 times) and dynamic nuclear imaging (twice for 30 minutes with a break of 15 minutes in between) procedures during their stay at the study center for approximately 8 hours (during which time the IntelliCap is expected to have reached the cecum). During dynamic nuclear imaging, subjects will be asked to remain in the same supine position during the image acquisition periods (2 times 30 minutes with a 15 minute break in between). One additional static nuclear imaging will take place at Day 2. Volunteers are asked to retrieve the IntelliCap after excretion in the stool and return it to the study center together with the portable unit. If the IntelliCap is not excreted by the Day 2 visit, subjects will be asked to continue wearing the portable unit and to come back to the study center once more to return the retrieved IntelliCap together with the portable unit. Similarly sized pills have been shown to have an extremely low risk of retention in the gastrointestinal tract in healthy human subjects. No other risks are anticipated related to the IntelliCap system.
Radiation exposure: The volunteer will receive 200 MBq 99mTc-pertechnetate orally by ingesting the Intellicap with a calculated effective dose of 3 mSv/ volunteer. 99mTc-pertechnetate has a short half-life of 6 hours. Additional details on the risk assessment of radiation exposure can be found in *Rechtvaardiging stralingsbelasting studieprotocol IntelliCap*.
Healthy volunteers will not have any medical or therapeutic benefit by participating in this study.

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

Healthy volunteers 18-55 yrs old,
Signed informed consent
Body Mass Index 18-30 kg/m2
All subjects must use a safe contraception method following ingestion of the IntelliCap (female subjects during one menstrual cycle or one month (whichever is longer), male subjects during 3 months)
Able to communicate well with the investigator, to understand and comply with the requirements of the study. Understand and sign the written informed consent

Exclusion criteria

Subjects with known or suspected gastrointestinal strictures, including (suspected) inflammatory bowel disease, ulcers, gastrointestinal or rectal bleeding or major abdominal surgery;
Subjects with pacemakers or other implanted electro-medical devices;
Subjects with swallowing disorders;
Pregnant or breastfeeding women;
Unwillingness to institute anti-contraceptive measures for the specified period;
Subjects using acid reducing medication;
Subjects using NSAID*s;

Subject with known cardiopulmonary or any other gastrointestinal disorders;
Subjects with ASA physical status classification system >1;
Subjects are not allowed to undergo MRI studies during the time the IntelliCap has not been excreted;
History of multiple and recurring allergies or present allergy or allergy to the investigational compound class / device materials being used in this study.;
Participation in a clinical research study within one month prior to participating in the current study;
Previous participation in any clinical research study with radiation exposure;
Subjects being unable or unwilling to provide informed consent, including legally incapacitated or institutionalized subjects

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2011
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	ingestion of an electronic device
Registration:	No

Ethics review

Approved WMO

Date:	23-02-2011
Application type:	First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL32762.041.10