Study of the pH profile in the human gastrointestinal tract, using an ingestible electronic device: the iPill

Published: 04-06-2010
Last updated: 04-05-2024

To study in healthy human volunteers safety of the iPill system. Secondary objectives are recording of pH and temperature of the gastrointestinal tract. To investigate the measurement and communication functionality of the iPill system

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

Summary

ID

NL-OMON34774

Source
ToetsingOnline

Brief title
Clinical study with iPill

Condition

- Other condition
- Gastrointestinal conditions NEC

Synonym
normal values temperature and pH digestive tract

Health condition

small bowel disorders

Research involving
Human

Sponsors and support

Primary sponsor: Philips
Source(s) of monetary or material Support: Philips Research;EIndhoven

Intervention

Keyword: digestive tract, human, ingestible electronic device, pH profile

Outcome measures

Primary outcome

Safety:

* recording any signs of iPill retention, gastrointestinal bleeding or

perforation

* studying structural and functional integrity of the iPIll after

gastrointestinal passage

Secondary outcome

Recording of pH, temperature and time during the iPill*s passage through the

gastrointestinal tract (max 26 hrs). Testing two way communications: sending

pH/temperature/time data to a remote data recorder worn on the subject*s body

and receiving a signal to reprogram the iPill*s behaviour reducing the

pH/temperature sampling frequency.

Study description

Background summary

Traditionally, the design of drugs for enteral delivery is based on chemical characteristics that determine the site of absorption. For example drugs that require absorption in the small bowel may have a coating that helps the drug to pass the stomach without being changed or absorbed. However, highly predictable delivery and exact dosing of drugs at specific sites in the gastrointestinal

(GI) tract is difficult to accomplish with the present drug delivery systems.
The iPill is a newly designed remotely monitored and controlled experimental electronic drug delivery device that may release the contents of a container into the gastrointestinal lumen at a location, based on information about changes of the intraluminal pH. Intraluminal pH follows a characteristic pattern. In the mouth and esophagus the pH is about neutral. In the stomach the pH is low because of the secretion of gastric acid. Upon passage through the pylorus the pH rises sharply because of the supply of bile and pancreatic juice in duodenum. From jejunum to distal ileum the pH rises slowly to about pH 7-7.5. In the colon the pH is somewhat lower. During passage through the ileo-cecal valve a drop of 1-1.5 pH is measured. By measuring pH, two marker points in the GI tract can be detected, namely the pylorus and the ileo-cecal valve. The residence time and drift velocity of larger particles is about constant (residence time 4-5 hours, drift velocity about 1 m/hour). In between the marker points the position of a device in the small intestines can be translated in time. E.g. two hours after a sharp rise in pH means 2 m from the pylorus.
The iPill system consists of an ingestible electronic device, a portable unit, a start-up unit and software. The iPill has three functions:
1. measuring pH and temperature in the lumen,
2. wireless two way communication in order to transmit the measured data to the outside world and to receive commands and
3. dispensing medication at a predefined location in the gut.
The portable unit relays wireless the information from the iPill to a control station and from the control station to the iPill. The software installed on the control station makes it possible to read out real time the measured data on pH and temperature and to control the medication dispensing of the iPill.
The iPill will be delivered in two parts, namely an electromechanical part and the medication container. Prior to use these two parts are clicked together and after that ready for use.

Study objective

To study in healthy human volunteers safety of the iPill system. Secondary objectives are recording of pH and temperature of the gastrointestinal tract.
To investigate the measurement and communication functionality of the iPill system

Study design

Observational study

Study burden and risks

The study requires ingestion of the iPill after an overnight fast and wearing a belt with a data recorder and relay unit for 26 hours. Volunteers need to come

to the study centre for a screening visit, at T=0 for ingestion of the iPill (total stay: 10 hours) and at T=26 hours. Volunteers are asked to retrieve the iPill after excretion in the stool. If they haven*t retrieved the iPill at the 26 hours visit, they should come back once more to return the retrieved iPill. Similarly sized pills have been shown to have an extremely low risk of retention in the gastrointestinal tract. No other risks are anticipated.

Contacts

Public
Philips

High Tech Campus 4(11)
5656AE Eindhoven
Nederland
Scientific
Philips

High Tech Campus 4(11)
5656AE Eindhoven
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy volunteers 18-55 yr old
Informed consent
Weight less than 100 kg.

Exclusion criteria

Subjects with known or suspected gastrointestinal strictures, including (suspected) Crohn*s disease
Subjects with pacemakers or other implanted electro-medical devices
Subjects with swallowing disorders
Pregnancy (females) or unwillingness to institute anticonceptive measures (males and females) until > 1 month after study termination
Subjects using acid reducing medication
Subjects using NSAID* s
Subject with known cardiopulmonary or any other gastrointestinal disorders
Subjects with ASA > 1

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):	20-07-2010
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	ingestion of an electronic device
Registration:	No

Ethics review

Approved WMO

Date:	04-06-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-07-2010
Application type:	Amendment
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	NL30492.041.09