Assessment of the Photopill Capsule Treatment for safety and feasibility in healthy volunteers, a phase 1 trial

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The evaluation of the safety and feasibilty of the Photopill capsule treatment in healthy volunteers, a phase 1 trial

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

Summary

ID

NL-OMON37258

Source
ToetsingOnline

Brief title
Photopill treatment, a phase 1 trial

Condition

- Other condition

Synonym
Inflammatory Bowel Disease, Ulcerative Colitis

Health condition

darmen van gezonde proefpersonen, uiteindelijk doel is darmonstekingen te behandelen

Research involving
Human

Sponsors and support

Primary sponsor: Photopill Medical Ltd.
Source(s) of monetary or material Support: Photopill Medical Ltd

Intervention

Keyword: Healthy volunteers, Phase 1 trial, Photopill, Therapy

Outcome measures

Primary outcome

* Safety evaluation of the device as determined by the number and severity of

Adverse Events in comparison to the baseline condition (Day 0 day 14, and

unscheduled visits]

* Comparison between baseline sigmoidoscopy assessments of mucosal appearance

of the rectal mucosa, and the follow up assessments of the treated area (Day 0,

Day 14).

Secondary outcome

not applicable

Study description

Background summary

Photobiostimulation, or Light therapy utilizes specific non-ionizing, non-thermal light wavelengths irradiation, by low intensity lasers (LLLT) or LED's, for the purpose of tissue healing for many skin and mucosal diseases that involve wounds, ulcers and inflammation.
Phototherapy has a proven positive effect not only on skin diseases, but on mucosal membrane as well. Such influence is described in several mucosal conditions and oral chemotherapy-induced mucositis in particular.
IBD is characterized by chronic tissue inflammation, tissue damage and ulcerations in various extents, and as such show considerable resemblance to many skin and mucosal conditions that are treated by light.
This observation suggest that photobiostimulation can be effective in treating

inflammatory gastrointestinal (GI) diseases and IBD in particular.
Photopill capsule has been developed specially for the treatment of IBD.
Therefore a phase 1 trial will probably be performed.

Study objective

The evaluation of the safety and feasibilty of the Photopill capsule treatment in healthy volunteers, a phase 1 trial

Study design

Open-label, interventional, independently controlled, clinical study

Intervention

After the rectum of the patient is cleaned with a Saline enema, the Photopill suppository capsule, mounted on a flexible rectal tube, will be inserted to the rectum till 10 cm. Finally the capsule will be activated.
Every 2 minutes, the rectal tube will be pulled out 1 cm distal to the previous location, and will be held in the new location for 2 minutes. The process will be repeated until 3cm colon mucosa is covered. 1 Treatmensession will constist of 5 sequential treatments with a 10 minutes break in between.
In total 2 treatment sessions will take place within 14 days. At day 0 and day 14 a sigmoidoscopy will be performed,

Study burden and risks

The main risk factor of the capsule is thermal damage of the intestinal mucosa due to light therapy.
This factor was examined during the pre-clinical studies in pigs and found to be non-significant.
Another side effect may be tissue erosion due to the insertion of the suppository capsule.
The rectal treatment sessions might be experienced as unpleasant and the same will possibly account for the repeating sigmoidoscopies.

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 or female subject between 18 and 65 years of age
Subjects who are generally healthy
Signed informed consent.

Exclusion criteria

Subjects with any known GI related symptoms complaints or GI diseases
Subjects with cancer or other life threatening diseases or conditions
Subjects with cardiovascular or pulmonary diseases
Pregnant women
Subjects who underwent any colon surgery
Morbid Obesity (BMI > 40)
Drug abuse or alcoholism
Bed-ridden Subject
Participation in current clinical study or clinical study within 30 days prior to surgery

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-08-2012
Enrollment:	4
Type:	Actual

Medical products/devices used

Generic name:	Photopill Capsule
Registration:	No

Ethics review

Approved WMO

Date:	28-08-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL40642.018.12

Study results

Date completed:	11-10-2012
Actual enrolment:	4