Assessment of the Photopill Capsule Treatment for Safety and Feasibility in Patients with Ulcerative Proctitis, a Pilot Study

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The evaluation of the safety and feasibilty of the Photopill capsule treatment in patients with Ulcerative Proctitis

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON40086

Source
ToetsingOnline

Brief title
Photopill treatment for Ulcerative Proctitis

Condition

- Gastrointestinal inflammatory conditions

Synonym
Inflammatory Bowel Disease, Ulcerative Colitis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Photopill, Therapy, Ulcerative Colitis, Ulcerative Proctitis

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 [Time Frame: Day 0 day 14, Day 28, Day 42 and unscheduled visits]

* Comparison between baseline sigmoidoscopy assessments of mucosal appearance of the diseased area, and the follow up assessments of the diseased area, according to the Mayo score [Time Frame: Day 0, Day 14, Day 28 and Day 42]

* Comparison of Clinical Questionnaires partial Mayo score and SSCAI at baseline and at day 42.

Secondary outcome

* Concentration of Inflammatory cells and mediators (cytokines, macrophages, and lymphocytes) in the tissue, as detected by histological assessment of biopsies taken from the diseased area . A comparison will be made between the baseline measurements and follow up measurements of the diseased area [Time Frame: Day 0, Day 14, Day 28 and Day 42]

* Comparison of inflammatory markers in serum (CRP) and stool (calprotectin) as collected at day 0 (baseline), 14, 28 and 42.

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.

Study objective

The evaluation of the safety and feasibilty of the Photopill capsule treatment in patients with Ulcerative Proctitis

Study design

Open-label, interventional, self-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 to the pre-determined distance(based on sigmoidoscopy data). 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 all the diseased area is covered.
In total 10 treatment sessions will take place within the first 28 days.
Follow-up will proceed untill day 42, when the last of the 4 sigmoidoscopies 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

* Diagnosed with Ulcerative Proctitis (Naïve or failing on stable dose of 5-ASA agents 8 weeks prior to day 0).
* Visible evidence for Ulcerative Proctitis in the rectum at the relevant treated area.
* Mild to moderate Ulcerative Proctitis Mayo grade 1 or 2
* Able and willing to travel 3 times a week to the clinic.
* Subject willing to sign an Informed Consent
* 18

Exclusion criteria

* Symptomatic hemorrhoids
* Pregnant or lactating females
* Patients that have used any experimental treatment within 8 weeks prior to Day 0
* Patients that have used any biologics therapies and/or steroids 4 weeks prior to Day 0
* Rectal therapy 2 weeks prior to Day 0
* Dose change in immunosuppression (azathioprine, 6-MP) in the previous 3 months

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-01-2013
Enrollment:	8
Type:	Actual

Medical products/devices used

Generic name:	Photopill Capsule
Registration:	No

Ethics review

Approved WMO

Date:	04-12-2012
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-03-2014
Application type:	Amendment
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	NL39583.018.12