

Topical treatment of perianal dermatitis with potato protease inhibitor cream in children after colorectal surgery.

Published: 07-03-2016

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To address the hypothesis that a potato derived protease inhibitor cream significantly limits perianal dermatitis in patients after colorectal surgery.

Ethical review	Not approved
Status	Will not start
Health condition type	Anal and rectal conditions NEC
Study type	Observational non invasive

Summary

ID

NL-OMON44063

Source

ToetsingOnline

Brief title

Pediatric Potato study

Condition

- Anal and rectal conditions NEC

Synonym

Congenital anomalies of the anorectum

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: pediatric colorectal surgery, perianal dermatitis, protease inhibitor

Outcome measures

Primary outcome

Improvement of perianal dermatitis using the IAD score and recording with digital day light photographs at week 2 and week 4

Secondary outcome

Patients well-being (IT-QOL)

Stooling pattern as recorded in the diary

Study description

Background summary

Perianal dermatitis can be a persistent problem in patients after colorectal surgery. This dermatitis is very painful and difficult to treat, and as such is a major unmet medical need.

Study objective

To address the hypothesis that a potato derived protease inhibitor cream significantly limits perianal dermatitis in patients after colorectal surgery.

Study design

Open label observational pilot study

Study burden and risks

Risk for allergie therefore patients with known allergies are excluded

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

Infant
Colorectal surgery
Perianal Dermatitis resistant to current therapy
No allergies noted

Exclusion criteria

Not speaking Dutch or understanding the study design
Known medical allergies

Study design

Design

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

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Still to be made
Generic name:	Potato Protease Inhibitors 5% in cetomacrogol

Ethics review

Not approved	
Date:	04-02-2016
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
EudraCT	EUCTR2015-003553-17-NL
CCMO	NL53859.078.15