Onderzoek naar de werkzaamheid van Caphosol tegen mucositis bij kinderen met kanker.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24436

Source
NTR

Brief title
Caphosol and mucositis

Health condition

Hospitalised children with cancer therapy induced mucositis

Sponsors and support

Primary sponsor: Universitair Centrum van Groningen, Utrecht, VU en Leiden
Source(s) of monetary or material Support: eerste geldstroom (geld van ministerie van OC&W aan universiteiten) en derde geldstroom door Eusapharma (farmaceutische industrie)

Intervention

Outcome measures

Primary outcome

Days of mucositis > grade I.

Secondary outcome

1. Days of analgesic use;

2. Total dose of analgesics;

3. Peak level of mucositis;

4. Peak level of pain;

5. Number of days with pain (VAS score > 0);

6. Number of positive blood cultures;

7. Number of days with tube feeding;

8. Number of days total parental feeding;

9. Tolerability of the product.

Study description

Background summary

Due to more intensive chemotherapy, overall survival in pediatric oncology patients has increased dramatically over the last decades. With this increased survival, it has become even more important to optimize the quality of life during and after treatment. One of the important side effects in pediatric oncology is chemotherapy or radiotherapy induced oral mucositis. This mucositis is accompanied with decreased oral intake, (severe) pain, often with use of analgesics and hospital admission. Thus, it has a severe impact on quality of life. Co-incidental with chemotherapy induced mucositis is therapy-related neutropenia. Neutropenic patients with mucositis are at increased risk for systemic infection. In a case controlled study, patients with mucositis and neutropenia had four times the risk of septicaemia than neutropenic patients without mucositis. Until now, no clinically useful drugs are available to prevent or treat chemotherapy induced oral mucositis. Recently, Caphosol, a Ca 2+ / PO4 3- mouth rinse, became available to treat or prevent mucositis. Until now, only one clinical study has been performed which concerned adult bone marrow transplant patients receiving chemotherapy and or radiotherapy. In these patients, Caphosol used as prophylaxis reduced the frequency, intensity and duration of oral mucositis. No information is available about the prophylactic or therapeutic use in children treated with chemotherapy or radiotherapy. Nevertheless, Caphosol is licensed as medical device for the treatment and profylaxis of oral mucositis for all ages. Therefore, we will study the effect of the therapeutic use of Caphosol in cancer therapy induced mucositis in pediatric oncology patients in 4 academic pediatric oncology hospitals in The Netherlands.

Study objective

The null hypothesis will be that Caphosol does not decrease the number of days of mucositis > grade 1, whereas the alternative hypothesis is that it will decrease the number of days of mucositis > grade 1 with 50%.

Study design

Morbidity measurements:

Experienced nurses will take tests 2 times daily in the morning and the afternoon. The following items will be scored:

1. Mucositis, using the NCI CTCAE mucositis score3;

2. Pain score: VAS score4 and faces score5;

3. Pain medication: product, dosage;

4. Use of antibiotics and bloodcultures taken;

5. Use of tube and/or parenteral feeding;

6. Tolerability of the product.

Intervention

Study design:

Since it is not ethical to ask patients consent to enter the study when they present with mucositis in such a degree that it needs hospital admission and medication, another strategy has been chosen. All patients at risk to develop oral mucositis on basis of their chemotherapy treatment, will be asked to participate in the study, i.e. that they
will get either Caphosol or standard treatment when they are eligible for the study. When patients present in the hospital with oral mucositis fulfilling the inclusion criteria for treatment with mouth rinse, they will be randomised and get either study- or placebo mouth rinse.

After randomisation, the patient will get standard supportive care, plus study treatment (Caphosol or NaCl 0.9%, i.e. standard mouth rinse). Standard treatment will be according to the institutes protocol and includes adequate pain management, hydration management to guarantee optimal fluid / hydration state, meaning nasogastric tube feeding when possible, or intravenous (re)hydration with Dextrose, NaCl and KCl (plus TPN if necessary). Oral care includes brushing of the teeth 3 - 4 times per day if possible, and standard care according to

local policies. The patients will rinse their mouth with study rinse (Caphosol or NaCl 0.9%) 4 times daily, 1 minute with 50% of the solution (15ml), and than 1 minute with the other half (15ml). If this is not possible (for the smaller children or when it is too painful to get this amount of fluid
in the mouth), it is allowed to rinse with smaller portions until 30 ml in 2 minutes is reached. After rinsing, the rinse is to be spit out. The nurse on the ward will note the time and amount of mouthrinse. The alternative study treatment , NaCl 0.9%, also (as Caphosol) has a salty taste and is currently the standard treatment for oral mucositis. Rinse should be used 15 minutes before or after meals and before sleeping time. As long as the patient suffers from mucositis the treatment will be given.

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Eligibility criteria

Inclusion criteria

1. Age 4-18 years;

2. Cancer therapy induced oral mucositis;

3. Hospitalisation.

Exclusion criteria

1. Impossibility to rinse the mouth;

2. Previous study participation;

3. Previous Caphosol use.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2010
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion

Date:	15-06-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35477
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2250
NTR-old	NTR2377
CCMO	NL29501.042.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35477

Study results

Summary results
N/A