Pilotstudy;
The use of Gelclair film in children undergoing chemo and/or radiotherapy to prevent oral mucositis and improve quality of life.

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To study the effect of Gelclair mouth rinse on pain by oral mucositis as a consequence of chemo- and/or radiotherapy, with pediatric patients. Primary we look at the WHO gradation of oral mucositis. In second part we also look at the nutritional...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31933

Source
ToetsingOnline

Brief title
Gelclair use in pediatric oncology patients.

Condition

- Other condition

Synonym
pain, sore mouth

Health condition

pijn

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: afdelingsbudget van WA-KJC IHOBA

Intervention

Keyword: Gelclair, mucositis, Pain, quality of life

Outcome measures

Primary outcome

Pain score

WHO gradation of oral mucositis

Secondary outcome

days in hospital related to oral mucositis

weight loss

Enteral or parentral feeding related to oral mucositis

Number of times gelclair is applied/rinsed per day (compliance)

Study description

Background summary

The IHOBA (Immunology, Hematology, Oncology and Auto-Immune diseases) wards at the WA-KJC (Willem Alexander Children and Childhood department) treats children

with malicious disorders en benign hematological disorders, and sometimes a stem cell transplantation is necessary. The treatments includes chemotherapy en sometimes also radiotherapy. Besides hair loss, nausea and vomiting is oral and gastrointestinal mucositis one of the most common and interactive side effect of chemo- and/or radiotherapy.

Depending of the kind of malicious disorder, doses en type of chemo and/or radiotherapy experienced 40 % of the adult patients en more than 60 % of the pediatric patients de side effect oral or gastrointestinal mucositis.
Mucositis is associated with heavy pain, most off the time is strong pain medication necessary in the form of opiates. There is weight loss, because of the reduced oral intake. Sometimes it is necessary to start met tube-feeding, or parenteral feeding. At last gastrointestinal mucositis leads to diarrhea en infections of the intestine. This affects the quality off life. Damage of the mucosal en the cause of ulcers makes that the patient with low resistance accessible is for translocation of bacteria and viruses, what can cause life-threatening infections. Patients with oral mucositis and neutropenia are 4 times more at risk for infections than patients without neutropenia. De side effects can cause reduction of the chemo- and/or radiotherapy, but that has consequences for the result of the treatment.
Not only clinical disturbances are a consequence of the mucositis, but also financial burden, because of the higher amount of days in the hospital.

Despite all the effort, there are still no effective prophylaxes or treatment for oral mucositis. For now the treatment includes good mouth care and pain control, to reduce the bother of this side effect. Study*s at oral mucositis is focused on the adult patient in contrast with the fact that oral mucositis is seen more with the pediatric patients. Completed study*s and the study*s that are still open are focused on finding a prophylaxes for the oral mucositis, but they didn*t found a successful treatment yet. Meanwhile the pain and the bad nutritional state affect the quality of life strongly.
In the United State they use the oral rinse Gelclair when the patient has disturbances of pain with oral mucositis. There is no research outcome found about study*s with pediatric patients and Gelclair. Completed study*s are focused on adult patients with oral mucositis grade 3 or 4.

Study objective

To study the effect of Gelclair mouth rinse on pain by oral mucositis as a consequence of chemo- and/or radiotherapy, with pediatric patients. Primary we look at the WHO gradation of oral mucositis. In second part we also look at the nutritional state by looking at the weight(loss) en infection parameters, like fever. We also ask the children on the effect on quality off life.

Study design

Every pediatric patient on the IHOBA sub-clinical ward and the IHOB-policlinic at the WA-KJC, who is diagnosed with oral mucositis grade 1 t/m 4 is asked, after verbal and by letter approval, to participate on this pilot study. The patients are asked to use the mouth rinse by prescription. The treatment includes rinsing with the Gelclair for minimal 3 times a day. Children under the age of 4 can*t rinse, so for them it is enough to tough the ulcers with the Gelclair. Next to the use of the Gelclair we ask de parents (and the patients itself when the are older than 16 years old) to keep up a diary. When the parents are not able to speak or read the Dutch language, the nurses on the IHOBA wards are asked to fill in the diary.

The next subjects are looked at:
• mucositis grade by the WHO grading for oral mucositis,. At this point we also look at the duration and the course of the mucositis
• Pain score. By the pain score there is a distinction between age.
o 0-4 years * pain measurement according the POKIS-scale. The child is shortly, carefully observed on 7 behavior ratings. The pain score can vary between 0 and 7.
o 4-7 years * pain measurement by self report with the OUCHER-scale. 6 faces translate a level of pain. The pain score can vary between 0 and 5.
o 7 and older * pain measurement by self report. The patient is ask to descripe the pain in to a number what is comparable with his pain. The pain score can vary between 0 and 10.
• Pain medication. Which pain medication is used and in which dose,
• Fever. Temperature is measured 1 times a day in the morning. When the temperature is above 38,5 *C, the temperature is measured 3 times a day.
• Use of antibiotics. Which antibiotics and which dose.

To get an overall picture we also look at the next subjects:
• Was hospitalization or elongation of the hospitalization necessary in relation with the oral mucositis?
• Course of weight. Weight is measured at start of the use of Gelclair and after completing the use of Gelclair.
• Is tube-feeding started in relation with the oral mucositis
• How many times did the patient use the Gelclair, and for how long.
• Did the patient the mouth rinse as a rinse or are the ulcers touched with the rinse?
We ask the parents to answer these questions at the and of the use of Gelclair

To complete the study we also look at the next subject:
• witch kind of chemotherapy is used, and what was the dose
• did the patient receive radiotherapy, and what was the total dose
• when the patient had any ulcers, Did the nurse took a sample of these ulcer, to be sure that there was no underlying infection.
The researcher will check these subjects from the patient*s status en will be analyzed.

The control group does exist of 10 children who are diagnosed with oral mucositis grade1 t/m 4, in the last 4 months of 2007. This is a retrospective data collection.

Intervention

3x day rinse with Gelclair

Study burden and risks

Mild allergic reaction to gelclair may sporadically occur. These are of minimal risk to the patient related to the maximal benefit expected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

oncology patients aged 0-18 years registered with the IHOBA
mucositis grade 1-4 (WHO)
chemotherapy +/or radiotherapy treatment
written infromed consent

Exclusion criteria

non fluent Dutch speaking parents in the outpatient setting
known allergy for gelclair

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2008
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL21498.058.08