Cryoprevention of oral mucositis
Information for patients

Background
You have been diagnosed with lymphoma/multiple myeloma and will undergo an autologous stem cell transplantation. Infusion of stem cells is preceded by conditioning with cytostatics. One side effect which affects a majority of patients receiving this cytostatic infusion is ulceration of the oral cavity, known as mucositis. The sores can make food intake difficult and can also cause pain which may require pain relief. This state, which is believed to be caused by unwanted cytostatic damage to the oral mucous membrane, generally has its onset 3–4 days after completion of cytostatic infusion and can last up to 1 month. Today this can largely be prevented/relieved by continuously chewing ice during the cytostatic infusion.

Cooling results in reduced exposure of the oral mucous membrane to the cytostatics, which in turn can have the result that no sores arise. Certain patients can however find the ice cooling unpleasant. To reduce discomfort we want to investigate whether ice can be replaced with Cooral™ intended to cool the oral mucous membrane.

Aim
The primary aim of the study is to evaluate the ability of Cooral™, compared with ice, to prevent the rise of mucositis in connection with cytostatic infusion. To assess this, two equal-sized groups of patients will be compared. A test group will have cooling with Cooral™ and a control group will have cooling with ice.

Implementation
It will be decided by lot whether you will receive treatment with ice or Cooral™. If you choose not to take part in the study you will receive standard treatment with ice. Cooling with each method is estimated to last a maximum 3–6 hours (lymphoma) or 1.5 hours (myeloma).

During the study period the person responsible for the therapy will repeatedly inspect the oral mucous membrane to assess the degree and extent of mucositis. The oral cavity will be inspected three times a week for four weeks, which means 12 visits to the clinic if you are not an in-patient. Each assessment is estimated to take about five minutes. We also ask you to complete a diary where you answer questions in writing about your oral health and general health, and any difficulties you experience with intake of food and liquids, a quality-of-life questionnaire, and your subjective evaluation of the cooling method. The staff on the ward will help you with instructions on how to fill in the various documents.

What is expected of you?
- Follow the instructions of the care staff for cooling of the mouth before, during and after the cytostatic infusion.

- Complete a diary every day for about a month, complete a general quality-of-life questionnaire twice and make a subjective assessment of the cooling method once (myeloma) or 5–6 times (lymphoma).

- Make 12 visits for inspection of the oral cavity (if **not** hospitalized).

Advantages/risks
A thorough survey of the literature shows that temperature reduction with the aid of ice cooling decreases the occurrence of mucositis. Despite this, the use of cooling with ice has been limited in clinical practice.

There is therefore reason to study whether cooling of the oral mucous membrane with Cooral™ gives better protection against mucositis than ice and/or is tolerated better.

By taking part in the study you can contribute to the development of a new treatment method which can help future patients in a situation similar to the one you are in.

Management of data
The management of your personal data is regulated by the Swedish Personal Data Act (SFS 1998:204). The study will be monitored by KTA-Karolinska Trial Alliance and all data collected during your time in care will be documented and processed in a separate confidential register established for all study participants. Names and personal identification numbers will be replaced by a code list, which will be stored under lock and key, with access authorized only to those in charge of the study. Your responses and your results will be handled in such a way that no unauthorized person can access them. When data from the study are published, it will not be possible to identify any individuals. All data will be kept for 10 years to enable future controls.

Responsibility for personal data
The hospital is responsible for managing your personal data. By participating in the study you give access to your patient records for scrutiny. You can approach the respective personal data representative if you wish an excerpt of the personal data registered about you, and you can obtain help if necessary to make corrections.

Akademiska sjukhuset: tel: 018-611 33 20

Karolinska universitetssjukhuset: tel: 0700 02 84 60

Universitetssjukhuset Linköping: tel: 010-103 74 89

Universitetssjukhuset Örebro: tel: 019-60 272 75

Voluntary participation
Your participation is entirely voluntary and you are fully entitled to cease participation at any time you like during your treatment time. The study has been approved by the Ethical Review Board in Göteborg (dnr: 586-15).

If you have any questions or if you wish to discuss the study, contact your nurse on the ward. Those responsible for the study are (doctor at the respective department) along with Anncarin Svanberg and Java Walladbegi.

Contact details

Java Walladbegi, Reg. Dentist/PhD candidate
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 0735-98 97 54

Anncarin Svanberg, Reg. Nurse/Doctor
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751 81 Uppsala

 018-611 42 90/0706-99 75 55

Consent to participate in the study
Cryoprevention of oral mucositis

I have been informed orally and have read the above written information. I have been able to ask questions and have received answers. I consent to participate in the study and am aware that my participation is wholly voluntary, and that I can at any time, without explanation, terminate my participation without that having any effect on my future care.

Signature **Name in block letters**

Date

The above patient has been informed about the design and purpose of the study (completed by the care provider)

Signature **Name in block letters**

(Responsible care provider)

Date

NB. To be signed on the same day by patient and doctor

Cryoprevention of oral mucositis
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The child whose guardian you are has been diagnosed with lymphoma/multiple myeloma and will undergo an autologous stem cell transplantation. Infusion of stem cells is preceded by conditioning with cytostatics. One side effect which affects a majority of patients receiving this cytostatic infusion is ulceration of the oral cavity, known as mucositis. The sores can make food intake difficult and can also cause pain which may require pain relief. This state, which is believed to be caused by unwanted cytostatic damage to the oral mucous membrane, generally has its onset 3–4 days after completion of cytostatic infusion and can last up to 1 month. Today this can largely be prevented/relieved by continuously chewing ice during the cytostatic infusion.

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Signature **Name in block letters**

Signature Guardian 1 **Name in block letters**

Signature Guardian 2 **Name in block letters**

Date

The above patient has been informed about the design and purpose of the study (completed by the care provider)

Signature **Name in block letters**

(Responsible care provider)

Date

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