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# The effect of propolis on chemotherapy induced oral mucositis and bacteremia during oral mucositis

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 18/07/2012 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 07/09/2012 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 22/01/2019 | Digestive System | |

## Plain English summary of protocol

Background and study aims:
Chemotherapy for treating cancer can also cause swelling in the oral cavity (mouth) called oral mucositis, which is usually painful and can make eating, speaking or even sleeping difficult. Bacteria from the oral cavity can easily make their way into the blood stream and cause infections (bacteremia) or even blood poisoning (sepsis). Propolis is an easily available remedy, which patients often use for treating oral mucositis. We were trying to find out if we can reduce the incidence, duration and severity of oral mucositis, and if we can reduce the number of bacteremias caused by oral bacteria, if we asked patients to apply propolis to oral mucosa.

Who can participate?
Children diagnosed with cancer and treated with chemotherapy.

What does the study involve?
Regular check-ups of patients oral mucosa status after propolis applications and teeth brushing while on chemotherapy and analysis of blood samples for oral bacteria.

What are the possible benefits and risks of participating?
Patients gain instructions on proper teeth brushing and due to supervision also immediate correction of improper habits. At the end of the study, patients and medical staff gain the information on propolis effectiveness in oral mucositis treatment. There are no risks for the patients.

Where is the study run from?
Division of Oncology and Haematology, University Children's Hospital, Medical Centre Ljubljana.

When is study starting and how long is it expected to run for?
The study started in July 2007 and it is expected to be finished in July 2013.

Who is funding the study?
University Medical Centre Ljubljana, Slovenia.

Who is the main contact?
Tanja Tomaevič
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# Contact information

### Type(s)
Scientific

### Contact name
Mrs Tanja Tomaevič

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# Study information

### Scientific Title
A double blind randomised placebo controlled study of propolis effectiveness in the prevention and treatment of oral mucositis and in the prevention of bacteremia during oral mucositis in chemotherapy treated children

### Study objectives
Propolis applications on oral mucosa in chemotherapy treated children could:
1. Prevent oral mucositis
2. Shorten the duration and severity of oral mucositis
3. Reduce the incidence of viridans streptococcal bacteremia

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
National Medical Ethics Committee, Ministry of Health of the Republic of Slovenia, 28 August 2007, ref:128/03/07.
Update approved 10 June 2009, ref: 49/09/09

## Study design
Single centre double blind randomised placebo controlled study

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Chemotherapy induced oral mucositis

## Interventions
Oral care protocol:
1. To apply the propolis or placebo to the vestibular oral mucosa using a Micro tip applicator
2. To brush teeth twice daily, using a soft toothbrush (Curapx, Curaden International AG, Kriens, Switzerland) and fluoride tooth paste (Colgate-Palmolive Company, New York City, New York, USA) provided to patients free of charge.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome measure
1. Mucositis episodes frequency, mucositis episodes mean duration and mucositis episodes mean severity, assessed with modified Oral assessment guide (1=normal, 3=severe mucositis) for the period of the chemotherapy if it lasts less than 6 months or for the first 6 months of the chemotherapy.
2. Cases of bacteremia during oral mucositis episodes

## Secondary outcome measures
1. Number of total parenteral infusions
2. Analgesics during oral mucositis

## Overall study start date
01/07/2007

## Completion date

01/07/2013

# Eligibility

### Key inclusion criteria
1. Paediatric patients, aged 1-19 years, who had been diagnosed with cancer and had started chemotherapy
2. Informed consent

### Participant type(s)
Patient

### Age group
Child

### Lower age limit
1 Years

### Upper age limit
19 Years

### Sex
Both

### Target number of participants
50

### Key exclusion criteria
1. Allergy to propolis
2. Pre-diagnosed oral disease or therapy for oral disease

### Date of first enrolment
01/07/2007

### Date of final enrolment
01/07/2013

# Locations

### Countries of recruitment
Slovenia

### Study participating centre
**Frankopanska ulica 8**
ljubljana
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1000

# Sponsor information

**Organisation**
University Medical Centre Ljubljana (Slovenia)

**Sponsor details**
Zaloka cesta 7
Ljubljana
Slovenia
1000

**Sponsor type**
Hospital/treatment centre

**Website**
http://www4.kclj.si/

**ROR**
https://ror.org/01nr6fy72

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
University Medical Centre Ljubljana (Slovenia)

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/08/2013 | 22/01/2019 | Yes | No |