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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
18/07/2012		☐ 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

Contact details

Frankopanska ulica 8 ljubljana Slovenia 1000

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

- 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

Key secondary outcome(s))

- 1. Number of total parenteral infusions
- 2. Analgesics during oral mucositis

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

Upper age limit

19 years

Sex

All

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 Slovenia

1000

Sponsor information

Organisation

University Medical Centre Ljubljana (Slovenia)

ROR

https://ror.org/01nr6fy72

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Medical Centre Ljubljana (Slovenia)

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes