Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Satureja Hvrtnsz (carvacrol) on the severity of mucositis and pain in children undergoing chemotherapy: a randomized double-blind clinical trial. double-blind clinical trial.

Protocol summary

Summary

Oral mucositis is a common complication of chemotherapy in children with cancer. Mucositis, resulting in damage to the cells lining the mouth can cause painful inflammation and scarring. Savory Labiatae plants and Pierre traditional medicine as an analgesic and anti-infective effects have been noted. This study aimed to evaluate the efficacy of oral gel on oral ulcer pain and it is savory. The trial was double-blind and in phase two trials is to evaluate the effectiveness of oral gel Savory on 60 children undergoing chemotherapy Who were selected randomly and were divided into two groups of intervention and control groups and allocation was done in parallel. Children with a history of chemotherapy was 3-14 years and in the course of chemotherapy with oral ulcers and, if connecting to the ventilator Shdndantkhab were excluded from the study. In both treatment groups prior to treatment of mucositis continued, the intervention group and the control group Oral gel containing fennel extract 1% placebo gel after detection of oral mucositis twice daily for five days and topical used in the mouth. Since the beginning of the oral daily treatment for five days of lesion severity of oral mucositis using the WHO Ocher pain and pain intensity using a questionnaire recorded and compared results in the two groups that can be based on it is a less costly and less complications used to treat and prevent mucositis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061813691N7**
Registration date: **2016-08-15, 1395/05/25**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-08-15, 1395/05/25

Registrant information

Name
Mohammad Arshadi Bostanabad
Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-07-15, 1395/04/25

Expected recruitment end date

2016-12-15, 1395/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Satureja Hvrtnsz (carvacrol) on the severity of mucositis and pain in children undergoing chemotherapy: a randomized double-blind clinical trial. double-blind clinical trial.

Public title
Savory effect of mucositis and pain severity in children receiving chemotherapy: a randomized double-blind clinical trial.
Purpose
Treatment
Inclusion/Exclusion criteria
Entry criteria: full consciousness, admitted to Tabriz Children's Hospital Hematology and Oncology, treatment with chemotherapy drugs cause mucositis (cisplatin, cyclophosphamide and Mtvtrvksayd); at least three years and a maximum of fourteen years, not having the recurrent infectious waste oral, diagnosis (ALL, lymphoma and neuroblastoma). Exclusion criteria: children and parents not wanting to continue working; the death of the child; the child is connected to the ventilator, continuous use painkillers or opiates to relieve pain.As a result the treatment will be compared in the two groups that could be a less costly and less complications used to treat and prevent oral ulcers.
Age
From **3 years** old to **14 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Nursing and Midwifery Faculty، South Shariati Street، Tabriz
City
Tabriz
Postal code
5138947977
Approval date
2016-07-04, 1395/04/14
Ethics committee reference number
IR.TBZMED.REC.1395.282

Health conditions studied

1

Description of health condition studied
mucosit
ICD-10 code
K12.3
ICD-10 code description
Oral mucositis (ulcerative)

2

Description of health condition studied
pain
ICD-10 code
h57.1
ICD-10 code description
Ocular pain

Primary outcomes

1

Description
Mucositis
Timepoint
For five days following chemotherapy with oral ulcers
Method of measurement
Czech List View and questionnaire oral ulcers World Health Organization

Secondary outcomes

1

Description
pain
Timepoint
For five days following chemotherapy with oral ulcers
Method of measurement
Czech List View and tools Ocher pain

Intervention groups

1

Description
Following chemotherapy with oral ulcers detected in the intervention group adhesive gel containing 1% plant extract twice a day locally in the oral mucosa (on normal mucosa) for five days In addition to routine treatment for mouth ulcer gel adhesive will be applied and consumption of food should be two hours away, preferably at bedtime will be used.
Category
Treatment - Drugs

2

Description
After oral ulcers in the control group than in the placebo following chemotherapy plant extract is an adhesive-free gel topically on healthy mucosa of the mouth twice a day for five days taking part will be used along with routine treatments and adhesive gel food intake are two hours should be used, preferably at bedtime

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Children's Hospital of Tabriz

Full name of responsible person
Tahereh Alvndnzhad

Street address
Sheshgelan Ave.

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person
Dr. Rashidi

Street address
Vice Chancellor for research، Tabriz University of Medical Sciences،university Ave. Tabriz, Iran

City
Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for research, Tabriz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Arshadi Bostanabad Mohammad

Position
Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty