

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Double blind Comparision study on safty ang efficacy of Ketamin mouthwash in children above 7 years old with chemotherapy induced Mucositis

Protocol summary

Study aim

Safty and efficacy ot Ketamin mouthwash for Mucositis treatment

Design

Double blind randomized controlled trial

Settings and conduct

Childrenn admitted to oncology ward with Mucositis grade 3 or 4. They divided into 2 group. Case group who recieved Ketamin mouthwash. Control group recieved normal salin mouthwash

Participants/Inclusion and exclusion criteria

Children above 7 years old with chemotherapy induced Mucositis

Intervention groups

Rinsing Ketamin mouthwash 20mg/ ml 3 times a day in case group and normal salin in control group

Main outcome variables

Muvositus grading, Pain severity, Oal tolerance, Onset of effect. Duration of effect

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 7021

Email address

fmalek@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-23, 1398/01/03

Expected recruitment end date

2020-08-24, 1399/06/03

Actual recruitment start date

2019-05-22, 1398/03/01

Actual recruitment end date

2019-07-23, 1398/05/01

Trial completion date

2019-07-23, 1398/05/01

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201218049750N1**

Registration date: **2020-12-23, 1399/10/03**

Registration timing: **retrospective**

Last update: **2020-12-23, 1399/10/03**

Update count: **0**

Registration date

2020-12-23, 1399/10/03

Registrant information

Name

Fatemeh Malek

Scientific title

Double blind Comparision study on safty ang efficacy of Ketamin mouthwash in children above 7 years old with chemotherapy induced Mucositis

Public title

Ketamin mouthwash for Mucositus treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children above 7 years old with high grade Mucositus

Exclusion criteria:

History of psychosis, History of seizure History of allergy to ketamin

Age

From **7 years** old to **14 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data and Safety Monitoring Board

Sample sizeTarget sample size: **40**Actual sample size reached: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

Random allocation. A number of envelopes equal to the size of the sample size were prepared. Groups are divided into two categories A and B. Another person writes the letter A on the half erasers and the letter B on the other half. Take each envelope and receive A or B according to its classification

Blinding (investigator's opinion)

Double blinded

Blinding description

Pharmacology specialist prepared mouthwash. Each mouthwash encoded. Pharmacologist is the only person who aware of mouthwash containing. Mouthwashes will be taken by patient. At the end of trial, codes will be decrypted.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee in Research of Children's Health
Research Institute - Shahid Beheshti University of

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo
Blvd, Velenjak,

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2019-08-28, 1398/06/06

Ethics committee reference number

IR.SBMU.RICH.REC.1398.014

Health conditions studied**1****Description of health condition studied**

Chemotherapy induced oral Mucositis

ICD-10 code

K12.31

ICD-10 code description

Oral mucositis (ulcerative) due to antineoplastic therapy

Primary outcomes**1****Description**

Mucositis grading

Timepoint

1 hour after mouthwash rinsing, After each day of trial

Method of measurement

Mucositis grading by examination

2**Description**

Pain severity

Timepoint

1 hour after rinsing mouthwash. At the end of each day of trial

Method of measurement

Questionnaire

3**Description**

Oral Tolerance

Timepoint

1 hour after rinsing mouthwash. At the end of each day of trial

Method of measurement

Questionnaire

4**Description**

Mouthwash Onset of effect

Timepoint

1 hour after rinsing mouthwash, at the end of each day of trial

Method of measurement

Questionnaire

5**Description**

Mouthwash Duration of effect

Timepoint

1 hour after rinsing mouthwash, at the end of each day of trial

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 20 patients with mucositis gear 3 or 4 who rinse ketamin mouthwash 20 mg/5cc

Category

Treatment - Drugs

2

Description

Control group: 20 patients with mucositis grade 3 or 4 who rinsed normal saline mouthwash

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Childrens Hospital.

Full name of responsible person

Dr Maral Hejrati

Street address

Shariati street. Mofid childrens hospital

City

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Tehran

Postal code

15514- 15468

Phone

+98 21 2222 7021

Email

Fmalek@sbm.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Congenital pediatric Hematologic diseases

Full name of responsible person

Congenital pediatric Hematologic diseases. Beheshti university

Street address

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Email

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Congenital pediatric Hematologic diseases

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maral Hejrati

Position

Pediatric Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maral Hejrati

Position

Pediatric resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maral Hejrati

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Partial details of variables such as pain severity

When the data will become available and for how long

6 months after result publishing

To whom data/document is available

Medical researcher

Under which criteria data/document could be used

After result publishin

From where data/document is obtainable

Dr Maral Hejrati

What processes are involved for a request to access data/document

Email

Comments