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 abive 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

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
Name of organization / entity
Country
Iran (Islamic Republic of)
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+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

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 size
Target 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
Phamacology specialist prepared mouthwash. Each mouthwash encoded. Pharmacologist is the only person who aware of mouthwash containing. Mouthwashe will 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 rinisg, After esch 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
Questinnaire

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 geare 3 ir 4 who rinse ketamin mouthwash 20 mg/5cc
Category
Treatment - Drugs

2

Description
Control group: 20 matients with mucositis grade 3 or 4 who rinsed normal salin 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 chidrens hospital
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15514- 15468
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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
Shariati street. Mofid Childrens hospital
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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 varibles 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