Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of treatment of constipation-induced infection in patients with grade IIb, III skin burn

Protocol summary

Study aim

The aim of this study was to treat constipation in burn patients. Which in the guidelines this process takes place after three to five days, but in this study, one day is considered.

Design

This study was a parallel randomized controlled trial study design. The sample size of the study is 120 patients that will be assigned to intervention and control groups using simple randomization method.

Settings and conduct

Evaluate and prescribe daily interventions versus three and five days recommended in the guideline, to prevent wound infection caused by constipation. This study will be performed in Motahhari Burn Hospital of Iran University of Medical Sciences. Confirmed patients and hospitalization in burn and intensive care units will be followed for 3 days after receiving Intended interventions, in terms of outcomes. Because the intervention processes in the groups are completely different, the outcome assessor will be blinding of the type of interventions received by the participants.

Participants/Inclusion and exclusion criteria

Patients with grade III and IIb burns, with a burn percentage of 20 to 30, will be selected for the study. In addition, any selected patients with a history of neurological, psychological, diabetes, hypertension, trauma other than burns, and inflammatory bowel disease will be excluded.

Intervention groups

Patients in the intervention group are prescribed oral adult Bisacodyl tablet (40 mg), adult Bisacodyl suppository, c-lax tablet, and lactulose during the outcome assessment. Patients in the control group are also given oral Bisacodyl and Bisacodyl suppositories during the outcome evaluation if the patient does not respond, finally, the patient is given normal saline enema on the third day.

Main outcome variables

Evaluation of constipation status, wound infection, incidence of burn wound infection, incidence of constipation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201226049834N1**
Registration date: **2021-05-01, 1400/02/11**
Registration timing: **prospective**

Last update: **2021-05-01, 1400/02/11**
Update count: **0**

Registration date

2021-05-01, 1400/02/11

Registrant information

Name

Aliakbar Jafarian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of treatment of constipation-induced infection in patients with grade IIb, III skin burn

Public title

Evaluation of treatment of constipation induced infection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Grade IIb, III upper-lower limb burns Burn percentage between 20 to 30

Exclusion criteria:

History of neurological diseases including dementia, Alzheimer's, Parkinson's History of psychologic illnesses including known and treated depression and anxiety, mania and schizophrenia Any allergies to laxatives or enzymes used History of Inflammatory bowel disease and Irritable bowel syndrome Coma or loss of consciousness Moderate to severe water and electrolyte disturbance Simultaneous presence of other traumas other than burns Perineal or anal burns History of diabetes, hypertension, heart, respiratory, liver and kidney

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

After the participants were selected to study, we will use simple randomization method to assign to the groups for received intervention and placebo. The randomization process will be performed using Random Allocation software, and since this study consists of two groups, the allocation outputs of the participants will be identified by A and B so the assign of each patient in each group is unpredictable to other members of the research team. We will notify for the team manager after selecting each patient and they will send out each patient's intervention type based on the software output. In this process will be informed of the type of intervention of each patient only clinical caregiver in unfavorable clinical conditions of patients.

Blinding (investigator's opinion)

Single blinded

Blinding description

Single blinding was considered for this study. Due to the different process of interventions in the study groups, only the patient outcome assessor will be blinded of the type of patient interventions.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2020-11-11, 1399/08/21

Ethics committee reference number

IR.IUMS.REC.1399.797

Health conditions studied

1

Description of health condition studied

Constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Evaluation of patients' constipation status

Timepoint

Maximum three days and examination every 12 hours from the beginning of the interventions

Method of measurement

Examination and clinical questions

2

Description

Wound infection caused by constipation

Timepoint

Duration of hospitalization of patients in infectious wards and intensive care

Method of measurement
Clinical examination and laboratory results

Secondary outcomes

1

Description
incidence of burn wound infection
Timepoint
Duration of hospitalization of patients in infectious wards and intensive care
Method of measurement
Clinical examination and laboratory results

2

Description
incidence of constipation
Timepoint
Duration of hospitalization of patients in infectious wards and intensive care
Method of measurement
Patient records and clinical examinations

Intervention groups

1

Description
Intervention group: Patients in this group will be treated for symptomatic constipation according to the guideline. The procedure is as follows: One adult Bisacodyl tablet (40 mg) is given. If no defecated within six hours, take two more oral tablets, and if not observed within six hours, use an adult Bisacodyl suppository, and if no response after six hours, take two oral c-lax tablets in the same way as when taking Bisacodyl was prescribed and in case of no response to lactulose in the amount of 20 cc and in case of no response in the amount of 50 cc to the patient.
Category
Treatment - Drugs

2

Description
Control group: If the patient does not defecate for more than five days or the patient feels pain and discomfort from not defecating, the patient is first given two Bisacodyl oral tablets. If the previous treatment does not respond, the adult Bisacodyl suppository is given in two stages at 24-hour intervals, and finally the patient is given normal saline enema on the third day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mottahari Burns Hospital
Full name of responsible person
Aliakbar Jafarian
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Mottahari Burns Hospital, Valiasr St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Iran University of Medical Sciences
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

Iran University of Medical Sciences
Full name of responsible person
Aliakbar Jafarian
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not 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