

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Effect of eyes irrigation by brewed black tea on the onset of redness, inflammation and purulent secretion in patients hospitalized in intensive care units

Protocol summary

Summary

Methodology: The study is a clinical trial, double-team with randomized allocation groups, done in two medical centers. Forty patients hospitalized in intensive care units after adaptation with inclusion and exclusion criteria including the absence of any trauma or injury to the eye and absence of signs of the study will randomly allocate into two groups to participate in the study if they consent to do so. In the intervention group, in addition to usual ICU eye care routine, one cc of brewed black tea for each eye will be applied once a day for 7 days. In the control group with the same conditions, the physiologic serum of 1 cc will be used to wash the patients' eyes instead of tea. In both groups on days 1, 3 and 7 the patients' eyes will be monitored, with examination criteria such as redness, eye discharge and inflammation of the eye. Symptoms will be recorded then the target samples will be removed from the rest of the investigation. In performing this teamwork-based research, the intervention is done by the main researcher, the co-researcher is responsible for the patients' monitoring and the data will be analyzed by statistics adviser as blind people in a double-blind framework.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610209664N6**
Registration date: **2017-07-12, 1396/04/21**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-12, 1396/04/21

Registrant information

Name

Mitra Payami Bousari

Name of organization / entity

Zanjan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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+98 24 3315 6962

Email address

payami@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Zanjan University of Medical sciences

Expected recruitment start date

2016-01-26, 1394/11/06

Expected recruitment end date

2016-03-02, 1394/12/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of eyes irrigation by brewed black tea on the onset of redness, inflammation and purulent secretion in patients hospitalized in intensive care units

Public title

Effect of eyes irrigation by brewed black tea on eye inflammation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Lack of eye injury and trauma; lack of congenital eye disease; no symptoms of redness; swelling and discharge at the time of sampling. Exclusion criteria: need to tarsurafy; possible allergic to tea extract; need for using Immunosuppressive drugs; consent from the patient or the patient's parents participate in the study; transfer the patient or died during intervention.

Age

From **23 years** old to **83 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization using number assigned from one to forty, then using the table of random numbers. Blinding via Failure to inform patients about the type of washing solution and preventing the researcher and co-researcher from confrontation to intervention and patients monitor

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Office of Student Research Committee, School of Medicine, Zanjan University of Medical Sciences, employees town ,the end of the Mahdavi boulevard, Zanjan, Iran

City

zanjan

Postal code

4513956113

Approval date

2015-10-07, 1394/07/15

Ethics committee reference number

ZUMS.REC.1394.185

Health conditions studied

1

Description of health condition studied

Symptoms include redness, inflammation and purulent secretion

ICD-10 code

H57.9

ICD-10 code description

Disorder of eye and adnexa; unspecified

Primary outcomes

1

Description

Eye inflammation

Timepoint

Days 1st, 3th and 7th from the onset of the study

Method of measurement

Physical visit

2

Description

Eye purulent secretion

Timepoint

Days 1st, 3th and 7th from the onset of the study

Method of measurement

Physical visit

3

Description

Eye redness

Timepoint

Days 1st, 3th and 7th from the onset of the study

Method of measurement

Physical visit

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, in addition to usual ICU eye care routine including washing the eyes by artificial tears every six hours, 1cc of brewed black tea for each eye around ten o'clock in the morning will be applied once a day for 7 days.

Category

Prevention

2

Description

In the control group with the same conditions, in addition

to the routine eye care which includes washing the eyes by artificial tears once per each 6 hours, the physiologic serum of 1 cc will be used to wash the patients' eyes instead of tea in the morning about ten o'clock daily.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Vali-e-Asr Hospital

Full name of responsible person

Dr.rostamkhani

Street address

Hazrat Vali-e-Asr Hospital, after ValiAsr Sq., Zanjan, Iran

City

Zanjan

2

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital

Full name of responsible person

Dr. Mohammad Reza Jamshidi

Street address

Ayatollah Mousavi Hospital, Gavazng road, Zanjan, Iran

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Zanjan University of Medical Sciences

Full name of responsible person

Dr. Korosh Amini

Street address

Vice Chancellor for Research and Technology, Second floor, Building No.1, The Central building of Zanjan University of Medical Sciences, Azadi Sq., Zanjan, Iran

City

Zanjan

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, Zanjan 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

Name of organization / entity

Faculty of Nursing and Midwifery, Zanjan University of Medical Sciences

Full name of responsible person

Ghazale Sattari

Position

Master of science student in Critical Nursing Care

Other areas of specialty/work

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No. 4, Spher Alley, Kafayeh Amani Street, Shohada Sq.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan Faculty of Nursing and Midwifery, Zanjan University of Medical Sciences

Full name of responsible person

Dr.Payami Bousari

Position

Associate Professor Faculty

Other areas of specialty/work

Street address

Zanjan School of Nursing and Midwifery, at the end of Mahdavi street., Eemployees town.

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Person responsible for updating data

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Full name of responsible person

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Position

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Other areas of specialty/work

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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