Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the Effect of Green Tea Extract on the Duration of Wound Healing and Pain Caused by Hernioplasty Surgery in Patients Undergoing Hernioplasty Surgery

Protocol summary

Study aim

Evaluation of The Effect of Green Tea Extract on the Duration of Wound Healing and Pain Caused by Hernioplasty

Design

A Clinical Trial With Control Group, With Parellel Group, Double Blinded, Randomized, Phase 3 of 30 Patients, Block Randomization Function is Used for Randomization

Settings and conduct

In This Study, Green Tea Extract Ointment Will be Compared with Placebo. In This Study, a Randomized and Parallel Clinical Trial Will be Conducted in The Surgery Department of Imam Sajjad Ramsar Hospital from August 1401 to August 1402. The Studied Population Are Patients Who Underwent Elective Hernioplasty by a Surgeon with a Clinical Diagnosis of Uncomplicated Hernia. Before the Intervention and on The Seventh Day, One Month and Three Months After The Operation, The Patients Visited The Office for Follow-up

Participants/Inclusion and exclusion criteria

Elective Herniopalsty surgery, Informed Consent and Male Gender from The Entry Conditions and Complicated Hernia, Immunodeficiency (Whether Due to Drugs Such as Corticosteroids), Age Under 18 Years, BMI Over 30 kg/m2, Green Tea Sensitivity, Neuropathy, Diabetes Mellitus, The Patient's Inability to Communicate Addiction for Drug Use, not Using The Ointment Regularly and According to The Order (less Than Once a Day) and Taking Drugs Effective on Wound Healing During The Study Are The Conditions of non-Entry.

Intervention groups

Ointment of 1% Green Tea Extract Will be Applied Topically at the Rate of 2 cm Twice a Day for Seven Days on The Place of Stitches. In The Control Group, Placebo Will be Used as an Ointment. As Much as Possible, The Color and Smell of The Ointments Will be The Same.

Main outcome variables

The Primary Outcome Includes Scar Width and SBSES Score, and The Secondary Outcome Includes Pain According to VAS Criteria and Wound Complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230205057331N1**
Registration date: **2023-02-20, 1401/12/01**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-20, 1401/12/01**
Update count: **0**

Registration date

2023-02-20, 1401/12/01

Registrant information

Name

Maryam Zeinali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 5422 6334

Email address

m.zeinali@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-18, 1401/05/27

Expected recruitment end date

2023-08-18, 1402/05/27

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effect of Green Tea Extract on the Duration of Wound Healing and Pain Caused by Hernioplasty Surgery in Patients Undergoing Hernioplasty Surgery

Public title
Evaluation of the Effect of Green Tea Extract Ointment on Duration of Wound Healing and Pain After Hernioplasty: A Randomized Double-Blinded Clinical Trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All Male Patients with Inguinal Hernia All Patients Who Referred for Elective Hernioplasty
Exclusion criteria:
Age
From **18 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
The Block Randomization Method Will be Used. Blocks Will Consist of 5 People, According to the Sample Size of 30 People, 6 Blocks with 12 Cards (6 Cards for Each Group) Will be Used. By Selecting Each Block, 5 People Will be Placed in a Group.
Blinding (investigator's opinion)
Double blinded
Blinding description
In This Research, for the Purpose of Blinding the Study, the Drug and Placebo are Coded by the Pharmacist; In This Way, the Researcher and the Samples Will Know the Contents of The Package, also All the Evaluations Were Done by a Person Who Will not Know About the Type of Treatment Received by the Patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
Mazandaran, Tonekabon, Karim Abad
City
Ramsar
Province
Mazandaran
Postal code
4681885550
Approval date
2022-12-07, 1401/09/16
Ethics committee reference number
IR.MAZUMS.3.REC.1401.8505

Health conditions studied

1

Description of health condition studied
Evaluation of The Effect of Green Tea Extract on The Duration of Wound Healing and Pain Caused by Hernioplasty
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
scar width and SBSES score
Timepoint
Seventh day, one month and three months after surgery
Method of measurement
The Stony Brook Scar Evaluation Scale

Secondary outcomes

1

Description
intensity of pain
Timepoint
Seventh day, one month and three months after surgery
Method of measurement
Visual Analog Scale

Intervention groups

1

Description
Intervention group: 1% green tea extract ointment will be applied topically for 2 cm twice a day for seven days on the suture site
Category
Treatment - Drugs

2

Description
Control group: A placebo will be used as an ointment
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Sajjad Ramsar Hospital
Full name of responsible person
Maryam Zeinali
Street address
Mazandaran, Tonekabon, Karim Abad
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4681885550
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m.zeinali@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Mahsa Narenji
Street address
Enghelab Square
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4691710001
Phone
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m.narenji@mazums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Maryam Zeinali
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Maryam Zeinali
Position
Medical Student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

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Person responsible for updating data

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Position
Medical Student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Mazandaran, Tonekabon, Karim Abad
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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
Undecided - It is not yet known if there will be 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