

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 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

#### City

Ramsar

#### Province

Mazandaran

#### Postal code

4681885550

#### Phone

+98 11 5422 6334

#### Email

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

#### City

Ramsar

#### Province

Mazandaran

#### Postal code

4691710001

#### Phone

+98 11 5509 1124

#### Email

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

#### Street address

Mazandaran, Tonekabon, Karim Abad

#### City

Ramsar

#### Province

Mazandaran

#### Postal code

4681885550

#### Phone

+98 11 5422 6334

#### Email

m.zeinali@mazums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mazandaran University of Medical Sciences

#### Full name of responsible person

Dr Mohammad Hadizadeh Neisanghalb

#### Position

Assistant Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

General Surgery

#### Street address

Ramsar Imam Sajjad Hospital

#### City

Ramsar

#### Province

Mazandaran

**Postal code**

4691710001

**Phone**

+98 11 5509 1124

**Fax****Email**

h.of.mohammad@gmail.com

4681885550

**Phone**

+98 11 5422 6334

**Email**

m.zeinali@mazums.ac.ir

**Person responsible for updating data****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

**Street address**

Mazandaran, Tonekabon, Karim Abad

**City**

Ramsar

**Province**

Mazandaran

**Postal code****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