

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparative study on the effect of brushing with traditional wooden toothbrush and drinking coffee on the duration of postoperative ileus and duration of hospitalization in patients undergoing elective gastrointestinal surgery

#### Protocol summary

##### Study aim

The effect of brushing with a wooden toothbrush and coffee on the duration of ileus after gastrointestinal surgery

##### Design

Clinical trial with control group, with parallel groups, without blinding, randomized, Excel software rand function was used for randomization.

##### Settings and conduct

Patients will be divided into three groups of wooden toothbrush, coffee and control by permutation blocks with a size of 6 by 11 blocks. Patients will undergo elective gastrointestinal surgery after providing information and obtaining informed consent. In all three groups of patients, according to the clinical condition of each patient, standard postoperative ileus treatments will be performed. The wooden toothbrush group will use the traditional wooden toothbrush twice a day (morning and night) for 5 minutes from the morning after the operation. Patients in the coffee group will also receive 100 ml of bitter coffee 3 times a day (morning, noon and night) from the morning after surgery. The control and wooden toothbrush groups will drink 100 ml of water 3 times a day from the morning after the operation. Treatment is given to each patient until the end of the ileus symptoms. The researcher will be informed about the time of the first gas excretion and the time of the patient's first stool. The study is performed in Amin Hospital of Isfahan.

##### Participants/Inclusion and exclusion criteria

Admission requirements: Patients undergoing elective gastrointestinal surgery. Conditions for not entering the study: History of underlying diseases and inflammatory bowel diseases and allergies to coffee.

##### Intervention groups

The study consists of three groups of 22 people and

starts in the morning after surgery for one group of toothbrushes, for one group of coffee and for the control group the standard treatment of ileus.

##### Main outcome variables

Change in ileus duration, change in hospital stay

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211025052864N1**

Registration date: **2021-11-21, 1400/08/30**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-11-21, 1400/08/30**

Update count: **0**

##### Registration date

2021-11-21, 1400/08/30

##### Registrant information

##### Name

Ebrahim Esfandiari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 9501

##### Email address

esfandiari@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-06, 1400/08/15

**Expected recruitment end date**

2021-12-06, 1400/09/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparative study on the effect of brushing with traditional wooden toothbrush and drinking coffee on the duration of postoperative ileus and duration of hospitalization in patients undergoing elective gastrointestinal surgery

**Public title**

Comparative effect of wooden toothbrush and coffee on ileus after surgery

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Elective gastrointestinal surgery

**Exclusion criteria:****Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **66**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization, permutation blocks Patients will be divided into three groups of toothbrush stick, coffee and control by permutation blocks with a size of 6 by 11 blocks.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical

Sciences

**Street address**

Department of Anatomy, School of Medicine, Isfahan University of Medical Sciences, Hezar Jerib St., Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Approval date**

2021-10-13, 1400/07/21

**Ethics committee reference number**

IR.MUI.MED.REC.1400.578

**Health conditions studied****1****Description of health condition studied**

ileus

**ICD-10 code**

K56.7

**ICD-10 code description**

ileus, unspecified

**Primary outcomes****1****Description**

The first time to expel gas or feces

**Timepoint**

No specific timing

**Method of measurement**

Patient report

**Secondary outcomes**

empty

**Intervention groups****1****Description**

First intervention group: wooden Toothbrush group: Patients will use traditional wooden toothbrush twice a day (morning and night) for 5 minutes from the morning after surgery. The required wooden toothbrush will all be provided from the same type.

**Category**

Other

**2****Description**

Intervention group: Coffee group: Patients will receive 100 ml of bitter coffee 3 times a day (morning, afternoon and evening) from the morning after surgery. Coffee is made using simple instant coffee powder and all patients will use the same brand and company of coffee unit.

**Category**

Other

**3****Description**

Control group: For this group, the usual standard ileus treatment is performed and they receive 100 cc of oral water 3 times a day.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Amin hospital

**Full name of responsible person**

Ebrahim esfandiari

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Isfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ebrahim esfandiari

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Anatomy

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Web page address**<https://scholar.google.com/citations?user=cASPvvAAA>

AAJ

**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**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data can be shared

**When the data will become available and for how long**

After printing the results

**To whom data/document is available**

Everyone

**Under which criteria data/document could be used**

To treat patients

**From where data/document is obtainable**Dr. Ebrahim Esfandiari Contact phone: 03137929105  
Address: Isfahan, Hezar Jerib St., Isfahan University of  
Medical Sciences, School of Medicine, Department of  
Anatomy Postal Code: 81746-73461**What processes are involved for a request to access data/document**Upon submission of the request from the project  
manager, the documents will reach him within a  
maximum of two days**Comments**