

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

The effect of coffee consumption on improving bowel function after abdominal hysterectomy compared to routine nutritional regime

Protocol summary

Study aim

Effect of coffee consumption compared to control group on bowel function improvement after abdominal hysterectomy

Design

In the control group from the first day after surgery, routine procedures were performed after abdominal hysterectomy. Surgery In addition to routine procedures, the patient drinks 100 ml (5 g) of the branded coffee drink Nestle every 6 hours (up to 3 times). Block random sampling One-blind randomization The sample size calculated in each group is 17 persons. Including 15% drop in total of 40 people

Settings and conduct

The study will begin in teaching hospitals of Mashhad University of Medical Sciences. In the control group from the first day after surgery, routine procedures were performed after abdominal hysterectomy. Surgery In addition to routine procedures, 100 ml (5 g) branded coffee drink (Nestle) is consumed every 6 hours (up to 3 times) by the patient.

Participants/Inclusion and exclusion criteria

Patients who underwent abdominal hysterectomy due to benign disease (AUB, fibroma, adenomyosis) with less than 2 and a half hours surgery were included. Exclusion criteria: Allergies or allergies to caffeine compounds; Inflammatory bowel disease; Liver dysfunction; Heart arrhythmia; Chronic constipation (less than or equal to twice a week); History of bowel surgery; Abdominal radiotherapy or intraperitoneal chemotherapy history; Patient transfer to ICU after abdominal hysterectomy; Need to insert NGT during web immediately after hysterectomy; Hypertension;

Intervention groups

Intervention group receiving coffee and control group receiving coffee essence

Main outcome variables

The primary outcome to be considered is the time of the patient's first gas discharge. Secondary outcomes

include time to first bowel movements, time to first bowel movement, solid diet tolerance, length of stay, and postoperative complications until patient admission.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200116046153N1**

Registration date: **2020-04-04, 1399/01/16**

Registration timing: **prospective**

Last update: **2020-04-04, 1399/01/16**

Update count: **0**

Registration date

2020-04-04, 1399/01/16

Registrant information

Name

zahra behnam rassouli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3605 0557

Email address

zbehnam71@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

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
The effect of coffee consumption on improving bowel function after abdominal hysterectomy compared to routine nutritional regime

Public title
The effect of coffee consumption on improving bowel function after abdominal hysterectomy compared to routine nutritional regime

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing abdominal hysterectomy due to benign disease The duration of surgery is less than 2 and a half hours
Exclusion criteria:
Allergies or allergies to caffeine compounds
Inflammatory bowel disease Liver dysfunction Heart arrhythmia Chronic constipation History of bowel surgery Abdominal radiotherapy or intraperitoneal chemotherapy history Patient transfer to ICU after abdominal hysterectomy Need to insert NGT during web immediately after hysterectomy Hypertension

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Quadruple blocks produced by Randomization.com

Blinding (investigator's opinion)
Single blinded

Blinding description
Outcome assessors and patients are unaware of the allocation group due to placebo use, and using the A and B codes instead of the group names, the information analyst will also be blinded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Committee on Ethics in Biomedical Research

Street address

Tehran, Qods Town (West), between South Flamak and Zarafshan, Iran Sima Street - Central Headquarters of Ministry of Health and Medical Education, Block A, 13th Floor

City

Mashhad

Province

Razavi Khorasan

Postal code

1111111111

Approval date

2019-11-18, 1398/08/27

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.728

Health conditions studied

1

Description of health condition studied

Ileus after abdominal hysterectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

the time of the patient's first gas discharge

Timepoint

Every 8 hours after intervention

Method of measurement

The patient is instructed to announce the time of first gas excretion

2

Description

time to first bowel movements

Timepoint

Every 8 hours after intervention

Method of measurement

Control of the timing of the first intestinal movements by the researcher by checking the timing of the onset of intestinal sounds

3

Description

time to first defecation

Timepoint

Every 8 hours after intervention

Method of measurement

The patient is instructed to announce the time of first defecation

4

Description

time to solid diet tolerance

Timepoint

Every 8 hours after intervention

Method of measurement

Controlling patient solid diet tolerance time by a researcher

5

Description

length of stay in hospital

Timepoint

daily after intervention

Method of measurement

Controlling the number of days a patient is hospitalized by the researcher

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, in the morning after surgery, in addition to routine measures, 100 ml coffee drink (5 g) of Nestle branded coffee is consumed by the patient every 6 hours (up to 3 times).

Category

Prevention

2

Description

Control group: In the control group, from the first day after surgery, routine procedures are performed after abdominal hysterectomy and a solution containing 100 ml of edible color and essence of coffee is given three times every 6 hours up to three times.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Behnam Rassouli

Street address

Khorasan Razavi, Mashhad, Farsi Boulevard, Shahid Javan and Ali Shahidi Square, Knowledge and Health City

City

Mashhad

Province

Razavi Khorasan

Postal code

99191-91778

Phone

+98 51 3804 9051

Email

p.relationships@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Khorasan Razavi, Mashhad, University Street, Next to Hoveizeh Cinema, Qureshi Building, Vice-Chancellor for Research and Technology

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

vcresraech@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

zahra behnam rassouli

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Mashhad- Faramarz Abbasi Boulevard- Faramarz
Abbassi 51- No. 21

City

Mashhad

Province

Razavi Khorasan

Postal code

9197834791

Phone

+98 51 3605 0557

Email

zbehnam71@gmail.com

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

Mashhad University of Medical Sciences

Full name of responsible person

monire ghomian

Position

associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of Obstetrics and Gynecology, Imam
Reza Hospital, Ibn Sina St., Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3802 2608

Email

ghomiann@mums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

zahra behnam rasouli

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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City

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Postal code

9197834791

Phone

+98 51 3605 0557

Email

zbehnam71@gmail.com

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