Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 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 defication

Timepoint

Every 8 hours after intervention

Method of measurement

The patient is instructed to announce the time of first defication

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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Street address
Khorasan Razavi, Mashhad, University Street, Next to Hoveizeh Cinema, Qureshi Building, Vice-Chancellor for Research and Technology
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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
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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