The effect of coffee ingestion in prevention of post-operative ileus after caesarean section: A randomized placebo-controlled trial

Protocol of Thesis

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Introduction

Caesarian section delivery has become more prevalent than the vaginal delivery in Egypt. According to the Demographic and Health Survey (DHS) in 2014, 52 % of women in Egypt give birth by caesarian section. This makes the caesarian section one of the commonest abdominal surgeries in Egypt.

Many complications could occur after an abdominal surgery. So after a caesarian section, complications that are variable in its intensity could occur. One of the commonest but yet serious is the postoperative ileus. ***(Sunil et al, 2001).*** Postoperative ileus complicates 26-31% of caesarian section deliveries. ***(Teoh et al, 2007)***

Postoperative ileus is a predictable delay in gastrointestinal motility that occurs after abdominal surgery. Probable causes include disruption of the sympathetic/parasympathetic pathways to the gastrointestinal tract, inflammatory changes through multiple pathways, and the use of opioids for the management of postoperative pain. ***(Artinyan et al, 2011)***

Postoperative ileus is presented with nausea, vomiting, abdominal distention, abdominal tenderness, and delayed passage of flatus and stool. These symptoms would remarkably worsen the patients' quality of life, increase length of hospital stay, and increase costs associated with postoperative recovery. ***(Holte et al, 2002)***

Although ileus is so prevalent, preventative therapeutic options are still limited. Many trials have been made to prevent ileus, including administration of prokinetic drugs such as serotonin receptor antagonists ***(Toyomasu et al, 2011)***, neostigmine ***(Drake et al, 2016)***, alvimopam ***(Tan et al, 2007)***, and ghrelin agonists ***(Beck et al, 2014)***, early resumption of feeding ***(Zhuang et al, 2013)***, gum chewing ***(Ertas et al, 2013)*** and adequate pain control ***(Bragg et al, 2015)*** ,Unfortunately, none of these strategies has been completely successful.

Coffee is one the most popular drinks in Egypt and the whole world. Several researches were done worldwide to study the effect of the caffeine present in coffee and resumption of intestinal motility after various abdominal surgeries. ***(Brown et al, 1990) (Müller et al, 2012)***. Recently the effect of coffee on prevention of postoperative ileus after caesarian section was researched ***(Rabiepoor et al, 2017)***.

That's why we are concerned in our study to determine the efficacy of coffee in prevention of postoperative ileus.

Aim of the Work

This study aims to assess the value of drinking coffee in promoting intestinal motility and prevention of postoperative ileus after elective caesarean section.

Research question:

After elective caesarean section, can drinking coffee lead to early intestinal motility and prevent postoperative ileus?

Research hypothesis:

Drinking coffee promotes intestinal motility thus prevent postoperative ileus and improve the postoperative intestinal symptoms after elective caesarean section.

Primary outcome:

- A change in the number of hours for the patients to pass flatus for the first time after an elective caesarean.

Secondary outcomes:

- A change in the number of hours for the patients to have their first intestinal sound to be heard by a stethoscope.
- A difference in the number of hours for the patients to pass stool.
- A difference in the number of the patients' hospital stay hours.

Patients and Methods

This study will be conducted in the 1 year period starting from October 2017, at Ain Shams Maternity Hospital.

Patients:

Patients will be recruited from emergency unit and inpatient wards in Ain Shams University maternity hospital.

Inclusion criteria:

1- Caesarean section.

2- Spinal anesthesia.

3- Total surgery time less than 90 minutes.

Exclusion criteria:

1- Previous complicated abdominal surgery or caesarean section with extensive adhesions requiring extensive dissection or intestinal manipulation.

2- Intraoperative intestinal complications.

3- Intraoperative respiratory complication.

4- Chronic intestinal diseases: irritable or inflammatory bowel diseases.

5- Chronic diarrhea or constipation.

6- Using laxatives pre-operatively.

7- Known hypersensitivity to caffeine.

8- Thyroid or hepatic disease.

9- Cardiac arrhythmias.

Methods:

Study type:

A single blinded, randomized, placebo-controlled trial.

Sample Size Justification:

According to The number of samples was calculated according to a study by Müller et al, (2010) considering the power of 90%, confidence 95% and significant level of 0.05, the sample size needed is 544 cases, and with adding 10% for occasional cases' drop out so the total sample size would be 600 cases, divided into two groups, 300 patients each, one in the intervention group and the other is the placebo.

Study design:

This study will include 600 patients undergoing their caesarean section.

The study aims will be explained to all patients and an informed written consent will be taken.

All recruited patients will be divided into two groups according to a random selection by the primary researcher who consecutively will open sequentially numbered, opaque, sealed envelopes containing colored

cards, blue card group will represent the intervention group and the red card group will represent the placebo group.

Procedure:

- For all patients, the anesthetic used will be Marcaine® Spinal heavy 0.5% and fentanyl and for post-operative pain, ketorolac will be used.
- Through Pfannenstiel incision, transverse lower segment uterine incision is done, with the duration of the surgery not exceeding 90 minutes.
- Patients will not be permitted to drink or eat, except for the drink offered by the researcher, till passing flatus.
- Early ambulation was encouraged.
- A stethoscope will be used to detect the first intestinal movement each 15 mins after the surgery.
- The patients will be advised to notify the researcher when they pass both flatus and feces.

Intervention:

- The intervention plan will be performed within the first 24 hours after the surgery.
- Provided by the researcher within 10 minutes, patients will drink 100cc sugar-free coffee at 3, 6 and 9 hours after the surgery, and the control group will drink 100cc sugar-free decaffeinated coffee at the same intervals.
- No other liquid will be allowed till passage of flatus and feces in the first day of surgery.
- We will use Nescafe Gold ® coffee (10g per 100cc water) for all the patients in the intervention group.

- We will use Nescafe Gold DECAF coffee (10g per 100cc water) for all the patients in the control group.

History taking:

- Age, parity, gestational age at time of delivery.
- Cause of caesarean section.
- Any past medical history or drug intake.

THE TRIAL FLOW CHART

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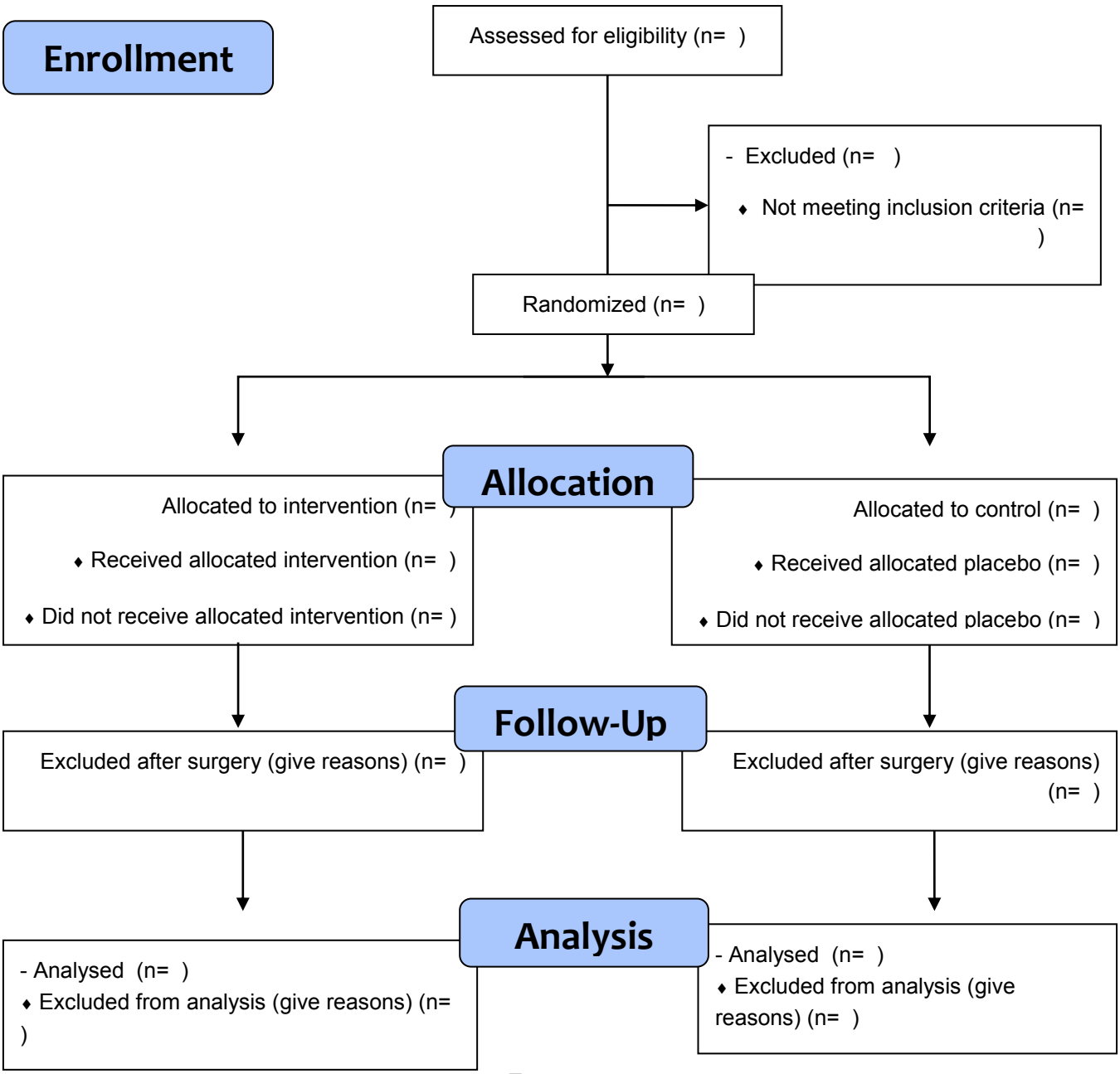

Data Analysis:

Data analysis will be performed by SPSS 16.0 using descriptive statistics tools, including mean, standard deviation and figures. A t-test will be used to compare mean values of the two groups. P-values, smaller than 0.05, were considered statistically significant.

Ethical and legal aspects:

Delegation of investigator responsibilities:

The investigator will ensure the all persons assisting in the trial are adequately informed about the protocol and their trial-related duties are well explained, and will maintain a list of sub-investigators and other appropriately qualified persons to whom significant trial related duties were delegated.

Patient information and informed consent:

Before being admitted to the clinical trial the patient must consent to participate after the nature, scope, and possible consequences of the clinical trial have been explained in a form understandable to her.

Confidentiality:

Only the patient file numbers and patient initials will be recorded in the case report form.

The researcher will keep a patient identification list (patient number and corresponding names and contacts) to enable records to be identified and enable records to be identified and allow communication with the patients.

Protocol approval:

Before beginning of the trial and in accordance with the local regulation followed, the protocol and all related documents will be declared for ethical and research approval by the Council of Obstetrics and Gynecology Department, Ain Shams university.

References

- Artinyan A, Nunoo-Mensah JW, et al. Prolonged postoperative ileus-definition, risk factors, and predictors after surgery. World J Surg 2008; 32(7):1495–1500.
- Beck DE, Sweeney WB, et al. Prospective, randomized, controlled, proof of concept study of the Ghrelin mimetic ipamorelin for the management of postoperative ileus in bowel resection patients. Int J Colorectal Dis 2014; 29:1527–34.
- Bragg D, El-Sharkawy AM, et al. Postoperative ileus: Recent developments in pathophysiology and management. Clin Nutr 2015; 34:367-76.
- Brown S, Cann P, et al. Effect of coffee on distal colon function. Gut. 1990; 31(4):450-3.12.
- Drake TM, Ward AE. Pharmacological management to prevent ileus in major abdominal surgery:a systematic review and meta-analysis. J Gastrointest Surg.2016 Apr 12.
- Ertas IE, Gungorduk K, et al. Influence of gum chewing on postoperative bowel activity after complete staging surgery for gynecological malignancies: a randomized controlled trial. Gynecol Oncol 2013; 131(1):118-22.
- Güngördük K, Özdemir IA, et al. Effects of coffee consumption on gut recovery after surgery of gynecological cancer patients: a

randomized controlled trial. Am J Obstet Gynecol 2017; 216(2):145.e1-145.e7

- Holte K, Kehlet H. Postoperative ileus: progress towards effective management. Drugs 2002;62(18):2603–2615.
- Müller S, Rahbari N, et al. Randomized clinical trial on the effect of coffee on postoperative ileus following elective colectomy. British Journal of Surgery. 2012; 99(11):1530-8.
- Rabiepoor Soheila, Yas Atefeh, et al. Does coffee affect the bowel function after caesarean section? Eur J Obstet Gynecol Reprod Biol 2017; S0301-2115(17)30362-7.
- Sunil S, Sinha S. Postoperative ileus: a preventable event (Br J Surg 2000; 87: 1480-93).British Journal of Surgery. 2001; 88(4):594-5.
- Tan EK, Cornish J, et al . Meta-analysis: Alvimopan vs. placebo in the treatment of post-operative ileus. Aliment Pharmacol Ther 2007; 25:47-57.
- Teoh W, Shah M, et al. A randomised controlled trial on beneficial effects of early feeding post-Caesarean delivery under regional anaesthesia. Singapore medical journal. 2007; 48(2):152.
- Toyomasu Y, Mochiki E, et al. Mosapride citrate improves postoperative ileus of patients with colectomy. J Gastrointest Surg 2011; 15:1361–67.
- Zhuang CL, Ye XZ, et al. Early versus traditional postoperative oral feeding in patients undergoing elective colorectal surgery: a metaanalysis of randomized clinical trials. Dig Surg 2013; 30:225-32.
