

# Does gum chewing enhance return of bowel movement after caesarean section?

<b>Submission date</b> 21/10/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/10/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 03/11/2008	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Karim H I Abd-El-Maeboud

**Contact details**  
Ain Shams University Maternity Hospital  
Abbassia  
Cairo  
Egypt  
11566

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**

Gum chewing and return of bowel motility after elective caesarean section: a randomised controlled single-centre trial

### **Study objectives**

Post-operative gum chewing enhances the return of bowel motility after elective caesarean section (CS).

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

This study was approved by the Ethics and Research Committee of Obstetrics and Gynaecology Department, Faculty of Medicine, Ain Shams University in June 2006.

### **Study design**

Randomised controlled single-centre trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Resumption of bowel motility after caesarean section (CS)

### **Interventions**

This trial took place at Ain Shams University Maternity Hospital. The participants will be randomly allocated to the following two groups:

1. Group I (study group): 93 patients will receive one stick of sugarless gum (Samarah Foods, Egypt) for 15 minutes starting two hours after end of CS and every two hours thereafter (during waking time, stopped during overnight sleep) until the passage of flatus or bowel movement
2. Group II (control group): 107 patients will receive traditional post-operative management, with oral intake of clear fluids and soft foods allowed after the passage of flatus and regular diet after bowel movement

For both groups, no subject will be given oral or rectal bowel stimulants after CS. The same post-operative rehabilitation programme for ambulation, excluding gum chewing, will be used for the control group. Auscultation for intestinal sounds will be performed at 4 to 6 hour intervals. The patients will be allowed to sip small amounts of water only 12 hours post-operatively. The oral intake of clear fluids and soft foods will be allowed when normal bowel sounds are detected and flatus has passed with advancement to a regular diet after passage of first bowel motion.

Eligible criteria for hospital discharge are stable vital signs with no febrile morbidity for at least 24 hours, ability to ambulate and urinate without assistance, passage of a bowel motion, ability to tolerate solid food without emesis and absence of unresolved other post-operative complications. For analgesia, two intramuscular doses of 75 mg diclofenac sodium (Voltaren®, Novartis Pharma, Egypt), a nonsteroidal anti-inflammatory medication, will be routinely given at 2 and 12 hours post-operatively. The need for additional use of narcotics (pethidine, 1 mg/kg) will be recorded.

The participants are to be followed-up by the study team until discharge from hospital. However, any side-effects, complication and unexpected events presented by the participants during the postpartum period (until 5-6 weeks after delivery) are also to be recorded.

## **Intervention Type**

Drug

## **Phase**

Phase III

## **Drug/device/biological/vaccine name(s)**

Chewing gum

## **Primary outcome measure**

With the time of end of surgery designated as zero hour:

1. The time interval to first hearing of normal intestinal sounds
2. The time interval to the first passage of flatus
3. The time interval to the first bowel movement
4. The time interval to the discharge from the hospital

## **Secondary outcome measures**

1. In Group I only: post-operative tolerance of gum chewing
2. In both groups: post-operative complications, including:
  - 2.1. Febrile morbidity (temperature greater than 38° C on two occasions 6 hours apart)
  - 2.2. Re-operation
  - 2.3. Blood transfusion
  - 2.4. Post-operative ileus. The occurrence of mild ileus symptoms (vomiting or abdominal distension felt by the patient and seen on examination) or post-operative paralytic ileus, defined as a group of manifestations persisting longer than 24 hours or requiring nasogastric tube placement. These manifestations include absent or hypoactive bowel sounds, non-passage of flatus or bowel movement, abdominal distension, more than three episodes of vomiting, with or without generalised crampy abdominal pain.
  - 2.5. Hospital readmission

## **Overall study start date**

01/07/2006

## **Completion date**

31/01/2007

## **Eligibility**

### **Key inclusion criteria**

1. Pregnant women set for planned elective CS under general anaesthesia
2. No age limits
3. Written and signed informed consent by the patient to participate in the study

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

200

**Key exclusion criteria**

1. Operation to be done not in the morning session
2. Patients undergoing caesarean hysterectomy or other extensive intra-abdominal surgery as a result of operative complication

**Date of first enrolment**

01/07/2006

**Date of final enrolment**

31/01/2007

**Locations****Countries of recruitment**

Egypt

**Study participating centre**

Ain Shams University Maternity Hospital

Cairo

Egypt

11566

**Sponsor information****Organisation**

Ain Shams University Maternity Hospital (Egypt)

**Sponsor details**

c/o Prof Karim H I Abd-El-Maeboud  
Abbassia  
Cairo  
Egypt  
11566

**Sponsor type**

Hospital/treatment centre

**Website**

<http://med.shams.edu.eg/index.php>

**ROR**

<https://ror.org/00p59qs14>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Ain Shams University Maternity Hospital (Egypt)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration