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# Gum chewing and the return of bowel motility after caesarean section under regional anaesthesia

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 02/02/2010 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 18/02/2010 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 18/02/2010 | Digestive System | [ ] Record updated in last year |

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

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
002

## Study information

**Scientific Title**
Post-operative gum chewing and the return of bowel motility after elective caesarean section under regional anaesthesia: a prospective randomised controlled trial

## Study objectives
In a recent study, gum chewing - as a form of sham feeding - after caesarean section (CS) under general anaesthesia was found to be safe, well tolerated, and associated with rapid resumption of intestinal motility and shorter hospital stay. In developed countries, CS is mostly performed under regional anaesthesia, and the numbers of such cases are increasing in our country. So, the aim of the present study is to investigate the effect of gum chewing on the return of bowel motility after elective caesarean section under regional anaesthesia.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics & Research Committee of OB GYN Department, Faculty of Medicine, Ain Shams University, approved on the 22nd December 2009

## Primary study design
Interventional

## Study design
Prospective randomised controlled trial

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Bowel motility

## Interventions
Following CS, patients will be randomised to two groups:
Group 1: 24 patients will receive one stick of sugarless non-sweetened gum (Samarah Foods, Cairo, Egypt) for 15 minutes every two hours after surgery until the passage of flatus or bowel movement.
Group 2: 24 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.

Total duration of treatment: about 24 hours (passage of flatus or motion) Total duration of follow-up: 1 week (first few days in hospital and by the end of first post-operative week in outpatient clinic)

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome(s)
With the time of end of surgery designated as zero hour, efficacy of gum chewing will be assessed based on shortened time interval to first hearing of normal intestinal sounds, to the first passage of flatus, to the first bowel movement, and to the discharge from the hospital.

### Key secondary outcome(s)
1. Recording of post-operative tolerance of gum chewing and post-operative complications, including febrile morbidity (temperature greater than 38°C on two occasions 6 hours apart), re-operation, blood transfusion, post-operative ileus, and hospital readmission
2. 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.

### Completion date
15/04/2010

## Eligibility

### Key inclusion criteria
1. Females aged 16 - 45 years
2. Set for planned elective caesarean section under regional anaesthesia
3. Written and signed informed consent by the patient to participate in the study

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Female

### Key exclusion criteria
1. Operation not to be done in the morning session
2. Patients with extensive lysis of adhesions of the bowel during CS
3. Patients undergoing caesarean hysterectomy or other extensive intra-abdominal surgery as a result of operative complication
4. Patients with severe post-operative haemorrhage or other post-operative complications requiring emergency interventions

### Date of first enrolment
15/02/2010

### Date of final enrolment
15/04/2010

## Locations

### Countries of recruitment

Egypt

**Study participating centre**
**2 Mobarak Str., Off Asmaa Fahmy**
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# Sponsor information

**Organisation**
Ain Shams University Hospitals (Egypt)

**ROR**
https://ror.org/00cb9w016

# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded (Egypt)

# Results and Publications

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

**IPD sharing plan summary**
Not provided at time of registration