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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Professor Karim Abd-El-Maeboud at kabdelmaeboud@yahoo.com to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
15/02/2010

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

Age group
Adult

Sex

Female

Target number of participants
48

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
Cairo
Egypt
11341

Sponsor information

Organisation
Ain Shams University Hospitals (Egypt)

Sponsor details
Obstetrics & Gynaecology Department
Abbassia
Cairo
Egypt
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Sponsor type
Hospital/treatment centre

Website
http://med.shams.edu.eg/maternity/

ROR
https://ror.org/00cb9w016

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (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