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

Submission date	Recruitment status	[ ] Prospectively registered
21/10/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/10/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/11/2008	Pregnancy and Childbirth	[ ] 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
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

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Egypt
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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