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Early oral feeding versus traditional route in patients with gastrointestinal (GI) anastomosis: a randomised controlled trial

Submission date 03/10/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 18/01/2006	**Overall study status** Completed	
Last Edited 16/10/2009	**Condition category** Surgery	

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

Study objectives
A period of starvation 'nil by mouth' is a common practice after GI anastomosis. The stomach is decompressed with a nasogastric tube and intravenous fluid is administrated. Then oral feeding begins after gastric dysmotility is resolved.
The rational of 'nil by mouth' is to prevent postoperative nausea and vomiting, in addition to providing the anastomosis some time before being stressed by food. In another words, patients are nil per os ('NPO') to prevent early complications (nausea and vomiting) and late complications of an anastomosis such as peritonitis, abscess and sepsis due to leakages of intestinal fluids into peritoneal cavity.
Contrary to the above opinion, there is evidence suggesting early feeding is beneficial.
It has been shown in animals that the 'NPO' period reduces the collagen content in anastomosed tissue and diminishes the quality of healing. Whereas feeding reverses mucosal atrophy induced by starvation and increases collagen deposition and strength of the site of anastomosis. Since a great number of GI surgeries are undertaken in malnourished patients, providing them with a chance to increase their depleted collagen storage after surgery is wise. Moreover, there are clinical investigations showing that early feeding is associated with improved wound healing and reduces septic morbidity after abdominal trauma and peritonitis. Some other studies suppose that early feeding minimizes the length of hospitalization. Additionally there are studies suggesting no significant difference in any feeding routes.
Most of the studies are surgical site specific. But this study takes all GI anastomosis into consideration, which might lead to a more general comment.
Considering the lack of data from Iran health providers on the matter, the study may also provide some help to choose more appropriate routes for our patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Different gastrointestinal pathologies lead to GI surgeries.

Interventions
Nasogastric tubes were removed immediately after surgery in both groups.
In group I (early feeding) patients, oral feeding began on the first postoperative day with liquid diet and gradually changed to normal diet as tolerated.
In group II (traditional route) feeding began with the same diet after resolution of ileus. That was defined by audible bowel sound plus no abdominal distension or vomiting.
In the case of vomiting more than twice, the nasogastric tube was reinserted in both groups.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Decreasing the early and late complications as below:
1. Early complications (inability to tolerate oral feeding, presented with nausea and vomiting)
2. Delayed complications (due to leakage from anastomosis, such as peritonitis, abscess and sepsis, in addition to fistula and death)

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2001

Completion date
01/03/2003

Eligibility

Key inclusion criteria
1. Being a candidate for GI anastomosis
2. Being a volunteer for participation

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants

150

Key exclusion criteria
1. Peritonitis
2. Albumin level <3 mg/dl
3. Age <4 years old
4. Previous history of autoimmune disease such as rheumatoid arthritis (RA) or systemic lupus erythematosus (SLE)
5. Previous abdominal surgery
6. History of endocrine disease
7. Diabetes mellitus
8. Heart valve diseases or atherosclerosis
9. History of surgery due to abdominal trauma

Date of first enrolment
01/03/2001

Date of final enrolment
01/03/2003

Locations

Countries of recruitment
Iran

Study participating centre
General Surgery Department
Tehran
Iran
16179

Sponsor information

Organisation
Imam Hossein University Hospital (Iran)

Sponsor details
Shaheed Madani St
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04esb6v42

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
It is an internally funded project by the General Surgery Department of Imam Hossein University Hospital (Iran)

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