

Gum chewing to prevent postoperative ileus after abdominal surgery; A multi-centre randomised single- blinded study.

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In the Netherlands, gum chewing has not been incorporated in the standard postoperative care after intra-abdominal surgery. Therefore a multi-center RCT was set up to evaluate the influence of gum chewing on the development of ileus. Our null...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Observational non invasive

Summary

ID

NL-OMON36453

Source

ToetsingOnline

Brief title

Gum chewing to prevent postoperative ileus

Condition

- Gastrointestinal conditions NEC
- Gastrointestinal therapeutic procedures

Synonym

gastrointestinal hypomotility, ileus

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: abdominal surgery, complications, gum chewing, postoperative ileus

Outcome measures

Primary outcome

length of hospital stay

Secondary outcome

complications untill 30 days postoperatively

time to flatus

time to defaecation

time to tolerance of normal diet

postoperative pain

Study description

Background summary

Postoperative ileus is common after intra-abdominal surgery. It is characterized by delayed passage of flatus and stool due to decreased bowel activity. Prolonged delay in bowel function may lead to patient's discomfort, lengthened hospital stay and hospital-acquired infections . Recently, a meta-analysis of 9 RCT*s on chewing gum after intra-abdominal surgery showed a significant reduction in postoperative hospital stay (1.1 days), time to passage of flatus and stool in the gum-chewing group. Also, the overall infectious complications were reduced in this group , but data on this subject were insufficiently reported. Although very promising, there is the possibility of publication bias because the results were based exclusively on small and heterogenic trials. Therefore a large well-designed randomized trial to compare gum chewing with standard postoperative protocol is warranted.

Study objective

In the Netherlands, gum chewing has not been incorporated in the standard postoperative care after intra-abdominal surgery. Therefore a multi-center RCT was set up to evaluate the influence of gum chewing on the development of

ileus. Our null hypothesis was that standard care and postoperative gum chewing were equal, the alternative stated that they would not.

The main objective was:

- What is the influence of gum chewing on the length of postoperative hospital stay (in hours)?

The secondary objectives were:

- What is the influence of gum chewing on the complication rate until 30 days postoperatively?

- What is the influence of gum chewing on time to flatus, defecation and diet tolerance (in hours)?

- What is the influence of gum chewing on postoperative pain perception?

Study design

Multicenter, single-blinded, randomized controlled trial in a clinical setting.

Study burden and risks

Little burden.

No side effects were mentioned in any of the RCT's on gum chewing daily fill in short questionnaire in diary

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

abdominal surgery

adult

Exclusion criteria

not able to obtain informed consent

children

acute surgery

Study design

Design

Study type: Observational non invasive

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-02-2011

Enrollment: 2000

Type: Actual

Ethics review

Approved WMO

Date: 28-10-2010

Application type: First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO

Date: 19-12-2011

Application type: Amendment

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO

Date: 08-03-2012

Application type: Amendment

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO

Date: 27-03-2012

Application type: Amendment

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO

Date: 16-04-2012

Application type: Amendment

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL30345.058.10