Perioperative Ketotifen as treatment for postoperative ileus

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25410

Source
NTR

Brief title
N/A

Health condition

Postoperative ileus
Postoperatieve ileus

Sponsors and support

Primary sponsor: G.E.E. Boeckxstaens
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Source(s) of monetary or material Support: G.E.E. Boeckxstaens
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Intervention

Outcome measures

Primary outcome

The predefined primary endpoint of efficacy is Delta (Ä) stomach retention (before and 24 h after operation). Stomach retention is formulated as the percentage of Technetium present in the stomach 2 h after the intake of a Technetium labeled pancake.

Secondary outcome

1) Colonic transit:

a) Scintigraphic determination of Geometrical Centre (GC) of postprandial intra-colonic mass 48 and 72 h postoperatively

b) 24 h colonic transit (i.e. delta GC between 24 h and 48 h after ingestion of 111In-DTPA labeled water)

c) Ä colonic transit (before and 72 h after operation).

2) Postoperative symptoms and signs:

a) time until ready for discharge

b) time until first flatus in h after surgery

c) time until first bowel movement in h after surgery

d) reinsertion of nasogastric tube

e) degree of postoperative pain, nausea, vomiting and abdominal cramping during the first 5 postoperative days

Study description

Background summary

Hypothesis

Perioperative ketotifen as treatment for postoperative ileus (POI).

Objectives

To characterize the beneficial effects of perioperative ketotifen on gastrointestinal transit time, clinical outcome measures, and the inflammatory response after abdominal gynaecological resections.

Study design and population

• Double Blind Randomised Controlled clinical trial.

• The study will be carried out in patients scheduled to undergo an abdominal gynaecological resection.

Inclusion criteria

18-80 years of age; median laparotomy

Exclusion criteria

• Preoperative therapeutic abdominal radiation
• Evident intra-abdominal inflammation (diagnosed by imaging and/or laboratory test results, including abscess or cholecystitis)
• Use of anti-allergic drugs
• Use of laxatives, prokinetic or anti-inflammatory drugs during the first 3 postoperative days.
• American Society of Anesthesiologists physical-health status classification (ASA-PS) >3
• Poorly regulated diabetes (>200 mg/dl (=11mmol/l))
• Colostomy or ileostomy, or intestinal resection as part of the surgical procedure
• History of epileptic seizures
• Functional constipation (Rome III criteria)

Outlay of Procedures

Anesthesia, analgesia, peroperative IV fluids, introduction of food and laxatives/prokinetics and respiratory support will be standardized according to a predefined protocol.

Drugs and dosages

Patients will be randomized to receive:

1) Ketotifen PO perioperatively (2 and 6 mg on the day before operation and 2 x 6 mg on the day of operation), and 12 mg ketotifen IP at the beginning and end of surgery

2) Placebo PO perioperatively and placebo IP at the beginning and end of surgery

Evaluation of effectivity

a) Patients will be studied scintigraphically on 5 occasions:

A baseline gastric emptying and colon transit scintigraphy using a small pancake labeled with 10 MBq 99mTc-Hepatate and 4 MBq Indium-111-diethylenetriaminepentaacetate (111In-DTPA) will be performed 2 weeks before the operation to establish the normal physiologic gastric emptying and colon transit for each individual.
22 h after surgery patients will be asked to eat a small pancake labeled with 10 MBq 99mTc-Hepatate. 2 h after ingestion gastric emptying will be measured once by scintigraphy.

Subsequently, patients will be asked to drink 150 ml of tap water labeled with 4 MBq Indium-111-diethylenetriaminepentaacetate (111In-DTPA). A baseline scintigraphic acquisition will be performed immediately after ingestion. Colon transit will be assessed 48 and 72 h after surgery.

In total seven 5-minute scintigraphic acquisitions will be performed.

b) Symptoms and signs of POI will be evaluated postoperatively by a standardized scoring questionnaire. In addition, time until ready for discharge will be assessed for each patient.

c) Determine levels or expression of pro- and anti-inflammatory mediators, including mast cell proteases/mediators in peritoneal lavage fluid and peripheral blood retrieved at the start and end of operation

d) Assess plasma- and peritoneal lavage fluid levels of ketotifen perioperatively and on the first postoperative day.

Parameters

Primary outcome measure:

The predefined primary endpoint of efficacy is Delta (Ä) stomach retention (before and 24 h after operation). Stomach retention is formulated as the percentage of Technetium present in the stomach 2 h after the intake of a Technetium labeled pancake.

Secondary outcome measures:

1) Colonic transit:

a) Scintigraphic determination of Geometrical Centre (GC) of postprandial intra-colonic mass 48 and 72 h postoperatively

b) 24 h colonic transit (i.e. delta GC between 24 h and 48 h after ingestion of 111In-DTPA labeled water)

c) Ä colonic transit (before and 72 h after operation).

2) Postoperative symptoms and signs:

a) time until ready for discharge

b) time until first flatus in h after surgery

c) time until first bowel movement in h after surgery

d) reinsertion of nasogastric tube

e) degree of postoperative pain, nausea, vomiting and abdominal cramping during the first 5 postoperative days

Study objective

Perioperative Ketotifen prevents and/or reduces postoperative ileus

Study design

pre- and postoperative

Intervention

Patients will be randomized to receive:

1) Ketotifen PO perioperatively (2 and 6 mg on the day before operation and 2 x 6 mg on the day of operation), and 12 mg ketotifen IP at the beginning and end of surgery

2) Placebo PO perioperatively and placebo IP at the beginning and end of surgery

And patients will be studied scintigraphically to determine gastroinstestinal transit

Contacts

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Eligibility criteria

Inclusion criteria

1. Gynaecological operation

2. 18-80 years of age

3. Median laparotomy

Exclusion criteria

1. Preoperative therapeutic abdominal radiation

2. Evident intra-abdominal inflammation (diagnosed by imaging and/or laboratory test results, including abscess or cholecystitis)

3. Use of anti-allergic drugs

4. Use of laxatives, prokinetic or anti-inflammatory drugs during the first 3 postoperative days

5. American Society of Anesthesiologists physical-health status classification (ASA-PS) >3

6. Poorly regulated diabetes (>200 mg/dl (=11mmol/l))

7. Colostomy or ileostomy, or intestinal resection as part of the surgical procedure

8. History of epileptic seizures

9. Functional constipation (Rome III criteria)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	26-05-2008
Enrollment:	58
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-02-2008
Application type:	First submission

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
NTR-new	NL1184
NTR-old	NTR1229
Other	: 2008-svb-1
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A