Perioperative Ketotifen as treatment for postoperative ileus

Gepubliceerd: 26-02-2008 Laatst bijgewerkt: 18-08-2022

Perioperative Ketotifen prevents and/or reduces postoperative ileus

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25410

Bron
NTR

Verkorte titel
N/A

Aandoening

Postoperative ileus
Postoperatieve ileus

Ondersteuning

Primaire sponsor: G.E.E. Boeckxstaens
Meibergdreef 9
1105 AZ Amsterdam
the Netherlands
020-5667375
g.e.boeckxstaens@amc.uva.nl
Overige ondersteuning: G.E.E. Boeckxstaens
Meibergdreef 9
1105 AZ Amsterdam
the Netherlands
020-5667375
g.e.boeckxstaens@amc.uva.nl

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

Perioperative Ketotifen prevents and/or reduces postoperative ileus

Onderzoeksopzet

pre- and postoperative

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Meibergdreef 9

Sjoerd Bree, van
Amsterdam 1105 AZ
The Netherlands
020-5662061

Wetenschappelijk

Meibergdreef 9

Sjoerd Bree, van
Amsterdam 1105 AZ
The Netherlands
020-5662061

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Gynaecological operation

2. 18-80 years of age

3. Median laparotomy

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	26-05-2008
Aantal proefpersonen:	58
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-02-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1184
NTR-old	NTR1229
Ander register	: 2008-svb-1
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A