

The role of ketotifen in the treatment of post-operative ileus

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
04/08/2005	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
04/08/2005	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
10/06/2008	Surgery	<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

The role of ketotifen, a mast-cell stabiliser, in the treatment of post-operative ileus

Study objectives

This is a randomised, placebo-controlled, double-blind study with patients who will undergo abdominal surgery. They will be treated with ketotifen 4 mg or 12 mg or placebo per day. The patient will start his medication intake three days before surgery until two days after surgery. Post-operative effectiveness will be determined by scintigraphy to look at gastric retention and colon transit. This scintigraphy will take place 24 hours after surgery. The patients will be clinically evaluated by filling out a daily symptom score list.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local ethics committee.

Study design

Randomised, placebo controlled, parallel group, double blinded trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Post-operative ileus

Interventions

Ketotifen 4 mg or 12 mg or placebo per day for three days before surgery until two days after surgery.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Ketotifen

Primary outcome(s)

Gastric emptying.

Key secondary outcome(s))

Symptoms.

Completion date

01/01/2006

Eligibility

Key inclusion criteria

Laparotomy for (malignant) process originating from colon or female reproduction organs.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Pre-operative radiation
2. Intake of medication with effect on the gastrointestinal motility
3. Intake of immunosuppressives
4. Intake of anti-allergy medication
5. Intra-abdominal inflammation (cholecystitis or abscess included)

Date of first enrolment

01/04/2004

Date of final enrolment

01/01/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Meibergdreef 9

Amsterdam

Netherlands

1105 AZ

Sponsor information

Organisation

Academic Medical Center (AMC) (The Netherlands)

ROR

Funder(s)

Funder type

Research organisation

Funder Name

The Technology Foundation (Stichting voor de Technische Wetenschappen) (STW-NOW) (The Netherlands)

Funder Name

Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration