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

Submission date 04/08/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 04/08/2005	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 10/06/2008	**Condition category** Surgery	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 effectivity 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 clinical 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

https://ror.org/03t4gr691

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