

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet**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 measure

Gastric emptying.

Secondary outcome measures

Symptoms.

Overall study start date

01/04/2004

Completion date

01/01/2006

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

48

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)

Sponsor details

Emma Kinderziekenhuis
Postbus 22660
Amsterdam
Netherlands
1105 AZ

Sponsor type

University/education

Website

<http://www.amc.uva.nl/>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration