The Orange III trial: Optimised recovery with Movicol preoperatively within an enhanced recovery programme, a randomised controlled trial

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The aim of this study is to accelerate recovery after liver surgery by enhancing intestinal passage through the preoperative use of Movicol®.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON40093

Source
ToetsingOnline

Brief title
Orange III trial

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary therapeutic procedures

Synonym
hepatic disease, Liverdisease requiring partial liver resection

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Norgine

Intervention

Keyword: ERAS, Liver, Movicol, Surgery

Outcome measures

Primary outcome

Primary outcome is recovery of gastro-intestinal function defined as time to

continuous intake of solid food for more than 24 hours.

Secondary outcome

Secondary outcomes are recovery of gastro-intestional function defined as time

to first stools and time to continuous oral intake of clear liquids for more

than 24 hours, functional recovery and hospital length of stay.

Study description

Background summary

The routine use of laxatives after liver surgery as part of an Enhanced Recovery After Surgery (ERAS®) programme enhances recovery of gastro-intestinal function and early tolerance of oral nutrition. The use of Macrogol (Movicol®) as laxative during one week prior to partial liver resection will further enhance early return of gastro-intestinal function and accelerate functional recovery.

Study objective

The aim of this study is to accelerate recovery after liver surgery by enhancing intestinal passage through the preoperative use of Movicol®.

Study design

The Orange-III trial is a multicentre randomised controlled trial to aim

whether the administration of 1 sachet of Movicol® during one week preoperatively and 2 sachets of Movicol® postoperatively will further enhance early recovery compared to the administration of 2 sachets of Movicol® postoperatively only, following liver surgery. All patients will be managed within an ERAS® programme of perioperative care.

Intervention

Patients randomised in group A receive once daily a sachet Movicolon®/Movicol® one week prior to partial liver resection. These patients should follow normal diet and are allowed to use prescribed co-medication in accordance to ERAS® protocols. Patients randomised in group B will not receive this daily sachet Movicolon®/Movicol® prior to liver surgery. As for Movicolon®/Movicol® postoperatively, both groups follow ERAS® protocols.

Study burden and risks

As the intervention (open partial liver resection) is well known and performed adequately and safely on a regular base, the burden and risks associated with participation in the trial are comparable with patients who are not participating in this trial. We foresee no risks associated with the investigational product. The benefits are an early return of gastro-intestinal function and thus an accelerated recovery of physical function and a decrease in risks of gastro-intestinal complications.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients undergoing a partial liver resection
- Able to understand the nature of the study and what will be required of them
- Men and non-pregnant, non-lactating women between age 18-80
- BMI between 18-35
- Patients with ASA I-III

Exclusion criteria

- Inability to give written informed consent
- Patients requiring bile duct reconstruction
- Patients with ASA IV-V
- Superextended hepatectomy
- Underlying symptomatic liver disease such as cirrhosis
- Underlying gastro-intestinal disease such as motility disorders
- Need for procedures additive to partial liver resection (including gastrojejunostomy)
- Participation in the ORANGE 2 trial
- Daily use of laxatives such as Movicolon®/Movicol®.
- Having diarrhea
- Hypersensitivety Movivolon
- Laparoscopic resection
- Concomitant HIPEC treatment

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2012
Enrollment:	44
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Movicol
Generic name:	Macrogol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	19-03-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	04-06-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	05-09-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	28-09-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-08-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-08-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-07-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
EudraCT	EUCTR2011-003129-92-NL
ClinicalTrials.gov	NCT01429779
CCMO	NL38131.068.11

Study results

Date completed:	01-09-2016
Actual enrolment:	75

Summary results
Trial is onging in other countries