Dipeptide Alanyl Glutamine and Postoperative Insulin Resistance in Colon Carcinoma Patients

Published: 18-03-2009 Last updated: 06-05-2024

The effect of the dipeptide alanyl-glutamine, intravenously or enterally and perioperatively given, on postoperative insulin resistance in colon cancer patients.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON35623

Source ToetsingOnline

Brief title AIRCo study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym

Insulin resistance, Temporary diabetes

Research involving Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar **Source(s) of monetary or material Support:** Fresenius Medical Care,Het Foreest instituut

1 - Dipeptide Alanyl Glutamine and Postoperative Insulin Resistance in Colon Carcino ... 7-05-2025

van het Medisch Centrum Alkmaar; Fresenius Kabi Nederland

Intervention

Keyword: colon carcinoma, Dipeptide Alanyl glutamine, Insulin resistancy, surgery

Outcome measures

Primary outcome

Our primary objective is to reduce/prevent the postoperative insulin resistance in colon cancer patients by the intravenous or enteral and perioperative administration of the dipeptide alanyl-glutamine.

Secondary outcome

- The effect of the dipeptide alanyl-glutamine on intracellular signalling in muscle tissue.

- The effect of the dipeptide alanyl-glutamine on glutathione concentration in muscle tissue.

- The effect of the dipeptide alanyl-glutamine on the amino acid concentration in muscle tissue.

- The effect of the dipeptide alanyl-glutamine on the inflammatory response in the circulating compartment.

- The effect of the dipeptide alanyl-glutamine on antioxidant/oxidant

parameters in the circulating compartment.

- The effect of the dipeptide alanyl-glutamine on the inflammatory response in liver tissue.

- The effect of the dipeptide alanyl-glutamine on the

inflammatory response in fat tissue.

Study description

Background summary

It is well known that insulin resistance occurs after mediocre and intensive surgery, such as colon cancer surgery. Disturbances in insulin action negatively affect the postoperative recovery, either by prolonging the capacity of the body to regain normal function, or by increasing the metabolic stress and the risk for complications. Several studies have shown that focusing therapies on improving insulin resistance is successful. Experimental studies have shown that antioxidant agents, like glutamine (a precursor of glutathione), improve insulin sensitivity. The hypothesis of this study is that perioperative parenteral or enteral administration of glutamine, given as the dipeptide alanyl-glutamine, will reduce or prevent postoperative insulin resistance in colon cancer patients.

Study objective

The effect of the dipeptide alanyl-glutamine, intravenously or enterally and perioperatively given, on postoperative insulin resistance in colon cancer patients.

Study design

A double blinded, placebo controlled, randomised, pilot study at the Surgery Department of the Medical Center Alkmaar.

Intervention

Patients will receive glutamine intravenously or enterally, starting 24 hours prior to surgery, until 24 hours after surgery in the dosage of 0.5 g/kg/day, or receive a placebo, normal saline, for the same period of time in equal amount.

Study burden and risks

Risks: Surgical site infection, bleeding and hematoma due to the biopsy Burden: 2 periods of 7 hours for the clamp method

Contacts

Public

3 - Dipeptide Alanyl Glutamine and Postoperative Insulin Resistance in Colon Carcino ... 7-05-2025

Medisch Centrum Alkmaar

Wilhelminalaan 12 1815 JD Alkmaar NL **Scientific** Medisch Centrum Alkmaar

Wilhelminalaan 12 1815 JD Alkmaar NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age between 18 and 75 year
- Colon cancer patients scheduled for elective open abdominal surgery
- Capable of giving informed consent

Exclusion criteria

- Patients who are participating in another clinical trial
- Unable to receive oral intake
- Major malabsorption disorder of the gut
- Patients with diabetes mellitus
- Use of certain medication: thyroid medication, corticosteroids, diuretic medication
- BMI above 30 kg/m2
- Known bleeding disorders or increased PTT and/or APTT

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	24-12-2010
Enrollment:	20
Туре:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	dipeptiven
Generic name:	alanylglutamine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	18-03-2009
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	09-04-2010
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO	

5 - Dipeptide Alanyl Glutamine and Postoperative Insulin Resistance in Colon Carcino ... 7-05-2025

Date:	18-10-2010
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Not approved Date:	23-03-2012
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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	EUCTR2008-007748-33-NL
ССМО	NL25981.094.08