A prospective, multicenter clinical study to evaluate the safety profile of the FlexiSurge Adhesion Barrier for the prevention of intra-abdominal adhesion formation after laparotomy

Published: 24-02-2014
Last updated: 24-04-2024

Aim of this study is to see if the use of an anti-adhesive medical device, the FlexiSurge, is safe to use against adhesions that arise after open abdominal surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40303

Source
ToetsingOnline

Brief title
FlexiSurge Study

Condition

- Other condition

Synonym
adhesion formation, postoperative adhesions

Health condition

vorming van adhesies na buikchirurgie

Research involving
Human

Sponsors and support

Primary sponsor: Medisse BV
Source(s) of monetary or material Support: Medisse

Intervention

Keyword: Adhesion, FlexiSurge, Laparotomy

Outcome measures

Primary outcome

Evaluation of Adverse Events reported during the study

Secondary outcome

Time to discharge; post discharge follow up; implant handling and macroscopical

features of the FlexiSurge Adhesion Barrier; Incidence, severity and extent of

the adhesions formed

Study description

Background summary

Postsurgical adhesions are a recognized clinical problem and can affect a majority of patients undergoing abdominal surgery. Fibrous tissue bands may start forming between surrounding tissue and organs or between organs, due to prosthetic, foreign materials, or other intrinsic and extrinsic factors which potentially can lead to major mid-term and long-term complications such as chronic pain, intestinal obstruction or secondary female infertility.

There are several prevention methods for reducing or avoiding adhesion formation after surgery. Most commonly, a barrier is placed around the treated tissue at the end of the surgery. In this way the growth of fibrous tissue from one trauma site (organ or surrounding tissue) to another traumatized or healthy site is interrupted and the adhesion formation halted.

The use of this FlexiSurge Adhesion Barrier may thus lead to a significant

reduction in the incidence, severity and extent of adhesion formation after major abdominal surgery.

Study objective

Aim of this study is to see if the use of an anti-adhesive medical device, the FlexiSurge, is safe to use against adhesions that arise after open abdominal surgery.

Study design

A prospective, multicenter clinical study.

Intervention

All patients will receive the standard of care before and after laparotomy. In addition, the patients will receive the FlexiSurge medical device as anti-adhesion barrier.

Study burden and risks

The normal risks that can occur with open abdominal surgery include thrombosis, lung inflammation, bleeding, pain and wound infections.

In this study, no additional invasive procedures need to be performed. All standard procedures that are the basis for a laparotomy will be applied. However, half of the participating subjects will also receive a FlexiSurge anti-adhesion medical device during the laparotomy. Furthermore, a pregnancy test needs to be performed.

The possible risks of the medical device used in this research in this form are not yet known. Since the medical device will be regarded as foreign and is biodegradable, it is plausible that a mild tissue reaction occurs during the decomposition process of the medical device by enzymes of the body.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

elective colectomy
elective colectomy with temporary stoma placement, followed by elective stoma reversal
elective liver first surgery, followed by elective surgical colectomy
ASA score 1-3

Exclusion criteria

previous surgery through abdominal incision
patients with a known history of adhesiolysis
BMI <=19 or >=35

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-06-2014
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	FlexiSurge Adhesion Barrier
Registration:	No

Ethics review

Approved WMO Date:	24-02-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-09-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-01-2015
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
CCMO	NL44765.068.13

Study results

Date completed: 11-05-2015

Actual enrolment: 5

Summary results
Trial ended prematurely