

Enterocutaneous fistula repair using the Biodesign enterocutaneous fistula plug (Cook Medical)

Published: 18-09-2013

Last updated: 23-04-2024

To evaluate the efficacy of Enterocutaneous fistula (ECF) repair using the Biodesign enterocutaneous fistula plug (Cook Medical).The primary objective of this study is to determine the feasibility, tolerance and primary technical success rate of...

Ethical review	Approved WMO
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON38559

Source

ToetsingOnline

Brief title

ECF repair with a Biodesign fistula plug

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym

abnormal connection between gut and skin, Enterocutaneous fistula

Research involving

Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biodesign fistula plug, Cook Medical, Enterocutaneous fistula

Outcome measures

Primary outcome

Technical feasibility of the treatment protocol, including: to determine the feasibility, tolerance and primary technical success rate of the

Enterocutaneous fistula repair using the Biodesign enterocutaneous fistula plug (Cook Medical)

Secondary outcome

The secondary objective will be to evaluate the longterm success (after 3, 6 and 12 months): permanent closure (non-production, skin healing) of the fistula.

Study description

Background summary

Enterocutaneous fistula (ECF) is an uncommon postoperative complication that places a significant burden on both the patient and the health care system. The management of this complication is complex and involves early recognition and control of sepsis, maintenance of adequate nutritional status, and protection of the skin. Multiple etiologies are associated with ECF formation. Most postoperative ECFs develop secondary to inflammatory bowel disease or malignancy. It may take months before an ECF heals, and some of them will never close spontaneously.

Study objective

To evaluate the efficacy of Enterocutaneous fistula (ECF) repair using the Biodesign enterocutaneous fistula plug (Cook Medical).

The primary objective of this study is to determine the feasibility, tolerance and primary technical success rate of Enterocutaneous fistula repair using the ECF-plug.

The secondary objective will be to evaluate the longterm success: permanent closure (non-production) of the fistula

Study design

A prospective, non-controlled single-institution pilot study.

Intervention

Percutaneous placement of Biodesign plug (Cook Medical) in enterocutaneous fistula according to protocol

Study burden and risks

Risk of CT: hypersensitivity to iodinated contrast medium, contrastnefropathy in patient with increased risk. These risk are equal to the risk of any other patient undergoing CT-scans

Risk of hypersensitivity to porcine material (therefore the procedure is contra-indicated in patients with a known hypersensitivity to porcine material.

Contacts

Public

Antoni van Leeuwenhoek Ziekenhuis

plesmanlaan 121
amsterdam 1066 cx
NL

Scientific

Antoni van Leeuwenhoek Ziekenhuis

plesmanlaan 121
amsterdam 1066 cx
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

A longstanding (more than 6 months) therapy-resistant (therapy according to AVL standard) low-output (less than 200 ml/ 24 hours) ECF.

Size of the ECF : 2/6-mm diameter, length less than 18 cm.

Exclusion criteria

Sensitivity to porcine materials.

An abscess cavity that is not sufficiently drained

An abscess cavity that is immediately adjacent to the internal fistula opening

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-05-2013

Enrollment: 10

Type: Anticipated

Medical products/devices used

Generic name: Biodesign enterocutaneous fistula plug (Cook Medical)

Registration: Yes - CE intended use

Ethics review

Approved WMO

Date: 18-09-2013

Application type: First submission

Review commission: METC NedMec

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	NL43289.031.13