VASCular no-REact® Graft Against INfection (VASC-REGAIN) Trial

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

Summary

ID

NL-OMON49830

Source
ToetsingOnline

Brief title
VASC-REGAIN trial

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Vascular therapeutic procedures
- Vascular disorders NEC

Synonym
vascular infection

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: BioIntegral Surgical Inc.

Intervention

Keyword: Bioprosthesis, Infection, Vascular

Outcome measures

Primary outcome

The primary endpoint of the study is graft infection at 3 months after implantation.

Related variables to be measured include:

1. Febrile or non-febrile status

2. WBC count

3. C-reactive protein (CRP) test

4. Samson classification of the infection (grade I-V) (for peripheral situations)

I. Infections extend no deeper than the dermis

II. Infections involve subcutaneous tissues but do not come into grossly observable contact with the graft

III. Infections involve the body of the graft but not at an anastomosis

IV. Infections surround an exposed anastomosis but bacteremia or anastomotic bleeding has not occurred

V. Infections involve a graft-to-artery anastomosis and are associated with septicemia and/or bleeding at the time of presentation

OR

CT findings (for central situations)

5. Patient temperature

6. Wound healing

7. Wound infection

8. If debridement was performed

9. Purulence

Secondary outcome

The second endpoint to be determined is patency at 12 months.

Related variables to be measured include:

1. Clinical assessment at 3 and 12 months

2. Duplex ultrasound (for peripheral situations) or CTA (for central

situations) at 3 and 12 months

Study description

Background summary

BioIntegral Surgical is a manufacturer of medical devices for cardiovascular surgery and produeces products which are all-biological and have a long and demonstrated history in fighting infection in cardiac, vascular and general surgery settings.

The No-React® Non-Valved Conduit (NRVC) is composed of a bovine pericardium sutured into a singleconduit or bifurcated conduit of variable diameters.

Like all BioIntegral products, the glutaraldehyde cross-linked conduit has been detoxified with a unique process. In contrast to conventional glutaraldehyde treatment, No-React® detoxified tissue does not leach detectable glutaraldehyde molecules and has been clinically proven to invite
endothelial cells to its surfaces which are in contact with blood. What*s more, the process also pacifies the tissue and creates a more permanent bond among the glutaraldehyde and collagen, ensuring improved long-term durability of the grafts. The No-React® process makes the xenograft
vessel tissue biocompatible, anti-infective, avoids coagulation and biological degeneration, all while retaining all the positive physical attributes of glutaraldehyde-treated tissues.

The No-React® Non-Valved Conduit (NRVC) is intended for use when there is a need for a biocompatible and infection resistant graft to replace infected

prostheses or to treat patients at high risk of (re)infection in the following locations: descending aorta, aorto-iliac, aorto-femoral and above-knee peripheral vasculature. There is no restriction on the age indication for this product.

Study objective

This study seeks to demonstrate the effectiveness and safety of the Non-Valved Conduit on the basis of infection. The rationale for infection resistance with the conduit is that Biointegral Surgical No-React® treated products have a well-documented history of infection resistance in hybrid vascular settings.

- Primary objective: Determine (re)-infection rate of the vascular conduit at 3 months following implantation in high infection risk patients or as a replacement for infected prosthetic graft.

- Secondary objective: Determine the patency rate of the vascular conduit at 12 months following implantation.

- Other objectives: Any adverse event * morbidity or mortality * is to be reported regardless if it is device or non-device related. In each case, the distinction between device and non-device related adverse event must be made.

Study design

This is a multicenter prospective intervention study which will require the inclusion of 60 patients from 10 vascular centers in the Netherlands.

Intervention

Included patients will have an operation for the implantation of the No-React® Non-Valved Conduit (NRVC) as vascular conduit.

Study burden and risks

Subjects can expect to have a lower risk of (re)infection, amputation and mortality.

There are no anticipated adverse device effects.

Residual risks related to the device are due to the nature of the product or the manufacturing process and have been classified as residual risks due to the serious, critical or catastrophic consequence. However, all of these residual risks are acceptable as per the risk analysis; no further risk control is possible without sacrificing the integrity of the device.

The risks associated with participation in the clinical investigation include are infection, thrombosis/thromboembolism, haemolysis, bleeding, stenosis, BSE and/or other possible contaminants and surgical risks. These risks can result in graft explantation, amputation, sepsis and/or death. However, the likelihood of these occurring is improbable or remote at worst. As per the risk analysis, the clinical benefits far outweigh the risks associated with participation, considering the expected urgent state of the subjects. The inherent design of the device and the implantation of
all possible controls minimize the probability of any of these events but they must be included due to their serious, critical or catastrophic consequences to the subject. The manufacturer does not expect any of these to occur in relation to the device.

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

Infected prosthetic graft and/or bifurcation, or
high risk of infection at graft implantation, or
mycotic aneurysm, and
no safe alternative available

Exclusion criteria

Below-knee bypass
AV access

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-12-2017
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	No-React® Non-valved Conduit
Registration:	No

Ethics review

Approved WMO

Date:	09-05-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-08-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-12-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-01-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-07-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-01-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL59973.100.16