Study of a novel implantable device to generate an autologous vascular graft for hemodialysis access

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The objective of the study is to assess the use of the Tissue Capsule for AV grafting in renal failure patients and testing these AV grafts for hemodialysis access.

Ethical review	Not approved
Status	Will not start
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON51014

Source
ToetsingOnline

Brief title
VACIS Rod

Condition

- Vascular therapeutic procedures

Synonym
AVF, Hemodialysis access

Research involving
Human

Sponsors and support

Primary sponsor: VACIS B.V.
Source(s) of monetary or material Support: Zie vraag G2 - bedrijf financierd het onderzoek

Intervention

Keyword: autologous, hemodialysis, vascular graft

Outcome measures

Primary outcome

Assess using the created TC as an AV access. Furthermore, the use of the graft for hemodialysis will be studied for outcomes without unexpected adverse events attributable to the TC during a total of 12 weeks. The primary endpoint of the study is the proportion of patients without unexpected adverse events attributable to the VACIS Rod and the TC.

Secondary outcome

Demonstrate the functionality of these AV grafts for hemodialysis access

- proportion of patients having functional dialysis cannulation

- proportion of patients having sufficient hemostasis after hemodialysis cannulation

To assess the 12 weeks patency of the TC as an autologous AV graft

- The primary and secondary patency of the arteriovenous access graft

1. Primary patency: number of days the graft stays open during the duration of the trial without needing intervention (other than anti-coagulants)

2. Secondary patency: number of days the graft stays open during the duration of the trial after intervention (other than anti-coagulants)

To assess the Tissue Capsule during this study on the objectives mentioned above

- Amount and type of interventions needed to maintain patency during study participation

- Qualitative assessment of the tissue capsule after 28 days by histology of the end caps

- Frequency of bleeding, necrosis, and infection complications during the study participation

- Time to hemostasis after removal of the dialysis needles

- Frequency of aneurysms of the graft

- Frequency of stenosis and/or intimal hyperplasia at the anastomosis sites

Study description

Background summary

A well-functioning arteriovenous (AV) access is the lifeline for dialysis patients. The AV access that is created for this purpose has a limited life span: next to the frequent puncturing there is a strong pressure component affecting the AV access with risk of aneurysm. Once an AV access is no longer functioning, a new AV access point has to be established. For this purpose, VACIS has developed a novel technology which makes use of the foreign body response to the VACIS Rod to create Tissue Capsules. These autologous Tissue Capsules can serve as replacement for the current AV access technologies.

Study objective

The objective of the study is to assess the use of the Tissue Capsule for AV grafting in renal failure patients and testing these AV grafts for hemodialysis access.

Study design

This is an open-label, prospective, single center study.

Intervention

Patients will be implanted with a sterile VACIS Rod through a small skin

incision into the subcutis with the exact location to be determined by the investigator, where it will stay for 28 days to form the TC. The rod will be implanted where the TC can be grafted to the artery and vein in-situ, after 28 days.
The VACIS Rod will be explanted 28 days after implantation and the tissue capsule will be anastomosed for AV access for a 2 weeks graft maturation period prior to hemodialysis cannulation.
Patients are followed for 10 weeks after graft maturation and start of hemodialysis cannulation.
The graft maturation period of 2 weeks may be adjusted if approved by the Principal Investigator.

Study burden and risks

The use of the VACIS Rod means a two-step procedure: first implanting the rod and 28 days later grafting the TC in the vasculature. This is an additional burden for the patient compared to the use of an artificial AV access.

The risks below may lead to failure of the TC for AV access and cause the burden of a new procedure to establish an arteriovenous access using an artificial AV access.

The risk for this trial is that the following events can happen:
* infection
* pain
* leaking anastomosis or graft
* lack of patency
* aneurysms
* thrombosis
* excessive bleeding
* scarring (comparable with the use of an artificial AV access)

The acute risk of thrombosis in the grafted TC is higher than for an artificial AV access and requires additional medication; however, after a short period of time an endothelial layer forms and the risk of thrombosis is reduced. The dual antiplatelet therapy to prevent thrombosis during the first six weeks after surgery has a slightly higher risk of causing bleeding than clopidogrel monotherapy, which is standard care after creating arteriovenous access with an AV access.

For non-terminal dialysis patients, an autologously grown AV access can provide a main alternative to the use of non-autologous prosthetic implants (artificial AV access). Prosthetic implants are associated with an increase in postoperative interventions and the risk of vascular graft infection. Therefore, these implants provide inferior results when compared to an autologous AV access. Hence the use of an artificial AV access is only considered when there are no autologous options available. The incidence of

postoperative interventions in patients with an artificial AV access in our group is around 2 interventions per patient year.

Compared to the use of AV accesses, the TC is expected to have better acceptance than non-autologous options, with a decreased risk of infection. The postoperative intervention rate is expected to be on the same level as in patients with an artificial AV access.
Lastly, the AV access created with the Tissue Capsule can be a life-saving treatment option for terminal dialysis patients, as other options may not be available anymore.

Contacts

Public
VACIS B.V.

Gaetano Martinolaan 63-65
Maastricht 6229GS
NL
Scientific
VACIS B.V.

Gaetano Martinolaan 63-65
Maastricht 6229GS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

For this study, we aim to include a total of 20 hemodialysis patients. Patients with a need for a arteriovenous access in whom only an AV graft can be considered or with a history of failed previous vascular access are considered to participate in this study. Patients are at least 18 and not older than 80 years old. To be eligible to participate in this study, a subject must meet the following inclusion criteria:
The patient:
1) is in need of hemodialysis according to the treating nephrologist
2) has a suitable location for an AV graft, preferably in the upper arm or forearm
3) is considered eligible for arteriovenous access surgery
4) has no suitable autologous options
5) has no hard contra-indication for antiplatelet therapy
6) is between and including 18 and 80 years old
7) is able and willing to give written informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1) Any concurrent illness, disability or clinically significant abnormality that may as judged by the investigator, affect the interpretation of clinical efficacy or safety data or prevent the subject from safely completing the assessments required by the Clinical Investigation Plan.
2) Current participation in another interventional clinical trial.
3) Patient with insufficient arterial blood flow (judged by an experienced clinician)
4) Patients with insufficient venous outflow and/or with obstructions (judged by an
experienced clinician)
5) History of anaphylaxis or severe allergic responses.
6) Treatment with systemic immunosuppressant drugs or patients which are immune depressed.
7) Women who are lactating, pregnant (positive pregnancy test at baseline) or planning to
become pregnant during the course of the study.
8) Signs of active infection, requiring systemic treatment or serious infection within the last
3 months based on patient screening data.
9) Poorly controlled diabetes mellitus (HbA1C > 75 mmol/mol Hb).
10) Current substance abuse or alcohol abuse. 11) Presence of vitamin K antagonists.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	Medical device to create a tissue capsule which is used for hemodialysis access
Registration:	No

Ethics review

Not approved

Date:	07-04-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL75486.042.20