

# Infectious complications following vascular surgery: Retrospective data analysis and prospective surveillance implementation in a tertiary referral center

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<b>Registration date</b> 13/01/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/06/2016	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Vascular disease is a term used to describe conditions that affect the heart and blood vessels (circulatory system). One of the most common types of vascular disease is stenosis (narrowing) of veins and arteries, due to the buildup of a fatty substance called plaque. This can lead to serious problems such as heart disease and stroke, and so the treatment of vascular disease is very important. Vascular surgery is widespread across the world. One of the most common types of vascular surgery is grafting, in which a superficial vein from elsewhere in the body or a prosthetic (artificial) graft is used to redirect blood flow around a narrowed or blocked blood vessel, restoring effective circulation. One of the most common complications after vascular surgery is infection. The likelihood that a patient will develop a post-surgical infection can be affected by a number of factors, such as other diseases the patient may have (comorbidities) and the processes used in the hospital where they are treated. The aim of this study is to review charts from elective (by choice) or emergency vascular surgery patients that have been treated in CHU Godinne UCL Namur between July 2015 and December 2015 in order to find out the amount of people who have suffered post-surgical infections and what the main causes are.

### Who can participate?

Adults who have had elective or emergency vascular surgery, in the second semester of 2015 or will have in 2016 at CHU Godinne UCL Namur (Belgium).

### What does the study involve?

Medical notes for all patients who have had vascular surgery involving venous or prosthetic vascular grafting in the second semester of 2015 are reviewed. Additionally, the medical notes for all patients who have had vascular surgery involving venous or prosthetic vascular grafting in 2016 are also reviewed. The amount of people who have had an infectious complication are recorded, as well as their medical history and treatment plan. Six months following surgery, patient notes are re-reviewed in order to find out how well they have recovered in the long-term.

What are the possible benefits and risks of participating?  
There are no direct risks or benefits to participants taking part in this study.

Where is the study run from?  
CHU Godinne UCL Namur (Belgium)

When is the study starting and how long is it expected to run for?  
January 2016 to June 2017

Who is funding the study?  
CHU Godinne UCL Namur (Belgium)

Who is the main contact?  
1. Dr Asmae Belhaj (scientific)  
2. Mr Marc Borgeois (public)  
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## Contact information

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Scientific

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## Additional identifiers

**Protocol serial number**

N/A

## Study information

### Scientific Title

Surveillance of Infectious Complications in patients undergoing a Vascular Surgery procedure: Prevalence, treatment, outcome

### Acronym

IC-f-VS

### Study objectives

The aim of this study is to evaluate our patient's preoperative medical status, and the rate, timing (early vs late) and severity of postoperative infectious complications, as well as the therapeutics management and outcomes.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics Committee CHU Ucl Namur, 07/06/2016, ref: B039201627251

### Study design

Single-centre retrospective and prospective observational cohort study

### Primary study design

Observational

### Study type(s)

Prevention

### Health condition(s) or problem(s) studied

Infectious complications of vascular surgery

### Interventions

Retrospective data of patients undergoing vascular surgery will be analysed for patients with vascular surgery in semester 2/2015. Prospective data will be registered for all patients undergoing vascular surgery in 2016. Data will be evaluated with a follow-up of 6 months following the date of surgery.

### Intervention Type

Other

### Primary outcome(s)

Infectious complication rates and severity (CDC definitions) measured by:

1. For retrospective data: reviewing of patient notes with a 6 months follow-up
2. For prospective data: ongoing medical surveillance with a 6 months follow-up

### Key secondary outcome(s)

1. Risk factors for infectious complications are measured using statistical analysis at the end of the study
2. Evaluation of therapeutic management is compared with internal guidelines at the end of the study
3. Patient outcomes are measured (infection resolution versus recurrence, amputation, mortality) with a 6 months follow up

**Completion date**

30/06/2017

## Eligibility

**Key inclusion criteria**

1. Aged 18 years or over
2. Vascular surgery patients receiving a venous or prosthetic vascular graft
3. Undergoing elective or emergency surgery

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

Patients with an infectious complication following vascular surgery performed in an external center.

**Date of first enrolment**

01/01/2016

**Date of final enrolment**

31/12/2016

## Locations

**Countries of recruitment**

Belgium

**Study participating centre**  
**CHU Godinne UCL Namur**  
Avenue Docteur Gaston-Therasse  
Yvoir  
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5530

## **Sponsor information**

**Organisation**  
CHU Mont-Godinne

**ROR**  
<https://ror.org/00ntbvq76>

## **Funder(s)**

**Funder type**  
Hospital/treatment centre

**Funder Name**  
CHU UCL Namur

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Available on request