Mannose-binding lectin (MBL) and post-operative complications/bypass patency with arterial operations

Published: 05-06-2012
Last updated: 28-04-2024

Demonstrate the possible difference in complications and bypass patency in certain large arterial operations with regard to the expression of the MBL-genotype.• Femoral/Crural

Ethical review	Approved WMO
Status	Will not start
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational invasive

Summary

ID

NL-OMON37369

Source
ToetsingOnline

Brief title
MBL and Bypass patency

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Mannose-binding lectin genotype, Post-operative complications

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Atrium medisch centrum zal de serumbuizen vergoeden. Bloedbepalingen zullen worden uitgevoerd in ander centrum dan Atrium Medisch centrum Heerlen. Danwel MUMC te Maastricht;ofwel LUMC te Leiden.

Intervention

Keyword: bypass patency, Mannose-binding Lectin, post-operative complications

Outcome measures

Primary outcome

The outcome were we will be particularly focus on are the genotype of MBL. Next to this are the post-operative complications (wound infections, re-operations, amputations etc.) correlated.

Secondary outcome

Possible secundair outcomes values are, recovery measured in time and eventually longer term comlications.

Study description

Background summary

In literature (see reference) the following things arise:
o Associations between MBL-deficiency and increased chance for infectious diseases are reported, also in healthy patients.
o Also stronger in patients with co-morbidities such as immunological disorders or chronic illness.
o These patients of MBL-deficiency have an increased chance for post-operative wondinfections and surgical complications.
o Patients undergoing a livertransplant, where the liver has the favorablde genotype, direct after surgery they show increased values in serum.
o This is also the other way around, so if the patient first has high expression, but the liver low expression. Direct after surgery the quantity in serum drops. This both is subject to to the fact that production takes places in the liver.
o The MBL-pathway provides activation of the classical pathway of the immune system respons, so if some patient is immune compromised en there is a lower expression of the MBL-pathway these patients have increased risk for complications
o Mutation in the MBL-gene have a significante negative impact on chronic illness, like reumatoid arthritis, SLE and cystic fibrosis, which results in increased incidence of complicated infections an worse outcome.

o The protective rol of MBL against infections can be explained by the direct binding of MBL to Micro-organisms.
o The concentration of MBL is many times higher in new onset diabetic in comparison with similar study patients.
o MBL is associated with vascular complications in diabetics, certain genotypes are significant more vulnerable to nefropathy
o In short, MBL can be associated with the pathogenesis of microvasculair complications.

Study objective

Demonstrate the possible difference in complications and bypass patency in certain large arterial operations with regard to the expression of the MBL-genotype.
• Femoral/Crural

Study design

patients undergoing a great arterial operation (Femoral/Crural). In front we will obtain informed consent and pre-operative we will obtain one bloodsample of heparenized blood for determining of the genotype. This determination will be done in de laboratorium.
All patients will be classified to risk factors, such as Diabetic mellilitis, smoking, cardi-vasculair diseases. Results from the research will be treated anonymous and confidential.

Study burden and risks

Considering that every patient pre-operative will get a infuse, there will not be any additional risk, while through this venous input on-off a heparinized serum sample for determining the MBL-genotype. In short there will not be any extra invasive action be carried out.

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

Patients with an arterial operation, whereby we will differentiate between femoral and crural.

Exclusion criteria

None

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	2000
Type:	Anticipated

Ethics review

Approved WMO Date:	05-06-2012
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL40451.096.12