FOreign body Reaction to bioMaterials and the Effect of Disease; inFORMED-trial

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Primary Objective: Examine the effect of disease on the responses to meshesSecondary Objective(s):- Compare the acute reaction of macrophages from patients at risk of adverse outcome (obese or aortic aneurysm) after implantation of meshes with the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON40901

Source
ToetsingOnline

Brief title
inFORMED-trial

Condition

- Other condition

Synonym
foreign body reaction

Health condition

lichaamsvreemde inflammatoire reactie

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: STW

Intervention

Keyword: foreign body reaction, macrophages, monocytes

Outcome measures

Primary outcome

-M1/M2 index

Secondary outcome

- Gene expression of M1 and M2 markers

- DNA levels as indication for the number of cells

Study description

Background summary

Foreign body reaction to biomaterials like meshes for hernia repair should be minimal. A mesh should successfully integrate in the body without causing massive inflammation and/ or fibrosis. Before a mesh can be used in the clinic, it is necessary to examine its effect on inflammation and fibrosis. For this, cell culture and animal experiments are used. In previous studies we have shown that culturing monocytes isolated from healthy donors on different meshes leads to a mesh specific reaction and that even in an in vitro model for contamination, meshes still elicit specific reactions in macrophages.

These two culture models are set-up with cells of healthy donors. It is known from the clinic however that certain groups of patients have increased risk for adverse outcomes after implantation of a mesh, such as obese, diabetic, smoking or old patients and patients with an aortic aneurysm. Age and disease affect the behavior of cells involved in wound healing and reaction to meshes.

Obesity for instance induces a phenotypic switch in adipose tissue macrophage polarization, from M2 (macrophages type 2, anti-inflammatory) to M1 (macrophages type 1, pro-inflammatory) activation and obese subjects have more total fibrosis in white adipose tissue and have more fibrosis around adipocytes

than lean subjects. In addition, recently it was found that macrophages from obese patients have less differentiation capacity towards an anti-inflammatory M2 phenotype.

The set-up culture models do not take these diseases into account and it is expected that cells from obese patients or patients with an aortic aneurysm will behave differently from cells from healthy subjects in their reaction to meshes. Therefore, we propose to use macrophages in our earlier set-up models.

The aim if this study is to investigate how disease affects the foreign body reaction and how cells from patients at risk for adverse outcomes respond to meshes in vitro. This knowledge can be used to choose the best performing meshes to be used in specific patient groups. This might eventually lead to a model that can be used to test several meshes using the patient*s own cells prior to implantation of a mesh.

Study objective

Primary Objective:
Examine the effect of disease on the responses to meshes

Secondary Objective(s):
- Compare the acute reaction of macrophages from patients at risk of adverse outcome (obese or aortic aneurysm) after implantation of meshes with the reaction of macrophages from healthy donors to meshes.

Study design

prospective study

In every group we will include 20 patients.
- 20 patients with BMI >30
- 20 patients with an aortic aneurysm >3cm (BMI between 18-27kg/m2)
- 40 volunteers, control

Study burden and risks

There is no serious extra risk for patients that are participating is this trial.

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

- Body Mass Index >30 kg/m2 OR aortic aneurysm >3cm OR healthy volunteer
- > 18 years
- signed informed consent

Exclusion criteria

- < 18 years
- BMI< 18kg/m2
- use of the following medication: immunosuppressive drugs, corticosteroids, chemotherapy recently.
- smokers
- Diabetes mellitus type I or II
- Patients who have a medical history like previous surgery or having a prosthesis e.g. heart valve, knee or hip replacement, mesh hernia repair, any kind of osteosynthesis material etcetera, all patients with any foreign body material should be excluded
- Patients who know or think that they might be infected with hepatitis B or C or HIV
- Patients with an autoimmune disease or chronic inflammatory disease.

- Patients who are anaemic or receiving treatment for anaemia or iron deficiency.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-11-2014
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	10-06-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL47780.078.14