Splenic Artery Injuries and the need for Vaccination after Embolisation

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To compare splenic function between patients who received splenectomy and patients treated with embolisation. Furthermore, splenic function between patients with different types of embolisation (proximal versus distal) will be compared

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

Summary

ID

NL-OMON39016

Source
ToetsingOnline

Brief title
the SAVE study

Condition

- Other condition
- Bacterial infectious disorders

Synonym
Splenic trauma; injury to the spleen

Health condition

letsel van de milt na trauma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: embolisation, splenic injury, trauma, vaccination

Outcome measures

Primary outcome

1. Immunological: the antibody response to polysaccharide antigens, before and after administration of the Pneumo-23® vaccine, and 2. haematological: the presence and quantification of Howell-Jolly Bodies in peripheral blood.

Secondary outcome

not applicable

Study description

Background summary

The spleen is one of the most commonly injured organs after blunt trauma and formerly splenectomy was the most applied treatment strategy. The risk of Overwhelming Post-Splenectomy Infection (OPSI), a disorder carrying a mortality of 50-70%, prompted the evolution toward more conservative treatment strategies for the treatment of splenic injury. Nowadays, Splenic Artery Embolisation (SAE) is increasingly being applied. Existing studies on immune function after SAE are not sufficient for any firm conclusions to be drawn about preservation of splenic immunocompetence. Furthermore, there has only been one study comparing splenic function between different types of embolisation (proximal versus distal) and very few patients were included in this study

Study objective

To compare splenic function between patients who received splenectomy and patients treated with embolisation. Furthermore, splenic function between patients with different types of embolisation (proximal versus distal) will be

compared

Study design

Experimental cohort study.

Intervention

Vaccination

Study burden and risks

Burden
Patients will be invited twice to the Academic Medical Centre (AMC). During the first visit, patients will be vaccinated with Pneumo-23® after the collection of blood samples (total of 24 ml). During the second visit, 14 days later, again a total amount of 24 ml blood will be drawn by a single venous puncture. Patients who are, for any reason, not capable to come the hospital will be visited by the researcher at home.

Risks
Overall, potential risks associated with participation in the study are categorised as *low risk*. A local haematoma may develop during blood sample collection. In addition, there is a chance of developing a local reaction (erythema, oedema, pain or tenderness) to vaccination. A small chance (0.1-1%) exists that other side effects of vaccination occur. Symptoms include fever, headache, myalgia and/or hypotension. This is not a severe complication since awareness and accurate treatment is available.

Benefit
This aim of this study is to investigate whether patients who receive different types of embolisation benefit from vaccination and to determine if this patient cohort should receive prophylactic immunizations in the future. Benefits include a protection against encapsulated bacteria and thereby a reduction in the risk of developing Overwhelming Post-Splenectomy Infection (OPSI).

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Adult patients (*18 years old)
* Treated with embolisation for splenic injury after trauma , * 6 months ago
* Master the Dutch, English or French language and fully able to understand the information provided
* Voluntarily written informed consent

Exclusion criteria

* Limited mental capacity or language skills such that explanations and instructions (regarding adverse events) cannot be followed
* Patients with splenic injury treated with observational management or splenic surgery (laparotomy with splenectomy or splenorrhaphy)
* Patients treated with a combination of proximal and distal embolisation
* Patients who have received a pneumococcal vaccine in the past 5 years
* Blood donation or blood loss greater than 400 ml in the last 3 months
* Participation in (an)other medical study(ies)
* Allergies for previously administered vaccines
* Patients with acute or chronic illness that may affect immunity
* Patients with comorbidity affecting splenic function (i.e. haematological or immunological diseases)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-08-2013
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	04-07-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL44733.018.13