Traumatic Splenic Injury and Management "Quality of Life and Clinical Outcomes of Treatment for Splenic Injury after Trauma" Prospective study

Published: 18-05-2016
Last updated: 17-04-2024

The primary objective of this project is to demonstrate the equivalence of treatment of traumatic splenic injury with splenic artery embolization (SAE) compared to splenectomy and non-operative management (NOM) in terms of quality of life at...

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

Summary

ID

NL-OMON47521

Source
ToetsingOnline

Brief title
SPLENIQ study

Condition

- Other condition
- Injuries NEC
- Therapeutic procedures and supportive care NEC

Synonym
Splenic injury, splenic laceration

Health condition

Quality of Life

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: Project Trauma TopZorg van ZonMw

Intervention

Keyword: Embolization, Quality of life, Spleen, Trauma

Outcome measures

Primary outcome

(II) PROSPECTIVE

PRIMARY

Quality of life is assessed with the generic 26-item World Health Organization Quality of Life-Bref (WHOQOL-Bref) [14] at 1 week, 1 month, 3 months, 6 months and 1 year follow-up. This measure assesses four domains (Physical health, Psychological health, Social relationships, and Environment) and a general facet *Overall QOL and general health*.

The short-form (12) health survey is a shorter version of the SF-36, which is used to evaluate individual patients health status, researching the cost-effectiveness of a treatment and monitoring and comparing disease burden.

iMCQ (iMTA Medical Consumption Questionnaire): The iMTA Medical Consumption Questionnaire (iMCQ), is a generic non disease specific instrument for measuring (direct) medical costs. The instrument is a standardized

self-reported questionnaire.

The iMCQ includes questions related to frequently occurring contacts with health care providers and can be complemented with extra questions that are relevant for specific study populations. A manual is available for a structured use of the questionnaire. Cost-prices be applied to the obtained healthcare utilization by the iMCQ by using the Dutch manual for cost-analyses that is written by iMTA on behalves of Zorginstituut Nederland (former CVZ). The iMCQ can be combined with the iMTA Productivity Cost Questionnaire (iPCQ). With the iPCQ indirect costs can be measured in addition to the direct costs as measured by the iMCQ.

iPCQ (iMTA Productivity Cost Questionnaire): The impact of disease on the ability of a person to perform work should be part of an economic evaluation when a societal perspective is applied. A manual is developed containing information on the modular
structure of the iPCQ and its scoring- and valuation methods that are used for the cost calculations. The iPCQ is a generic non-disease specific questionnaire and is applicable to national and international studies. Currently a Dutch version version of the iPCQ are available. Both indirect cost due to absenteeism as the productivity losses due to presenteeism (i.e. sick, but working) are taken into account. Different methods exist to value productivity. The human-capital method takes the patient*s perspective and counts any hour not worked as an hour lost. By contrast, the friction-cost method takes the employer*s perspective, and only counts as lost those hours not worked until

another employee takes over the patient*s work. By applying wage costs the results of the iPCQ can be monetized and as such used in health economic evaluations.

Secondary outcome

(II) PROSPECTIVE

SECONDARY

Furthermore the three treatments will be compared in terms of clinical outcomes, recovery related outcomes and cost outcomes. Also imaging outcomes will be investigated in the SAE group, thereby identifying morphological (versus immunological) aspects of the spleen after endovascular treatment.

The following endpoints apply to each of the outcomes:

- Clinical: complications during and/or after treatment; failure rate (technical, clinical); any re-intervention or additional therapy
- Recovery related: hospital stay (days); return to daily activities
- Cost: cost-utility analysis between SAE and splenectomy
- Imaging: how does the spleen morphologically look like, in patients who underwent embolization treatment of the splenic artery in case of traumatic splenic injury? Splenic morpholical characteristics such as: volume; necrosis; splenosis; calcifications; chronic infarction morphology

The cost effectiveness of SAE compared to splenectomy will be assessed using a Markov modeling approach taking into account uncertainty and using all available data. The effectiveness will be expressed in the most common outcome

measure the Quality Adjusted Life year (QALY). The costs will be estimated from a societal perspective.

For the cost-effectiveness study, data on quality of life, survival and costs are needed.

- Quality of life will be calculated by the SF-12
- Survival will be derived from international clinical literature
- Costs will be divided in direct medical costs and the costs due to productivity losses from a societal perspective. Costs are derived by multiplying the (health care) utilization or productivity loss by the reference price.
- Costs will be estimated according to the Dutch Manual for Costing in Economic Evaluations, update 2010 (Hakkaart-van Roijen, Tan& Bouwmans 2010).
- Health care utilization and production losses will be derived from various sources:

o questionnaires concerning patientÕs health care usage to be completed by patients: iMTA Medical Consumption Questionnaire (iMCQ), iMTA productivity costs questionnaire (iMPQ)

o hospital administrations for inpatient health care use will retrospectively be assessed

- International literature
- Expert opinion

A bottom-up methodology will be used to compute costs; total number of medical contacts will be multiplied with unit costs. Direct medical costs comprise all costs directly relating to the prevention, diagnostics, therapy, rehabilitation

and care of the intervention.

Direct medical costs include costs associated to hospital admissions, ambulatory hospital visits, medication, ambulatory care, medical aids etc. Direct costs outside the healthcare sector are directly related to the intervention, but generally do not incur within the formal healthcare system, such as travelling costs and time costs of patients and their informal caregivers. The shadow price method will be used to express informal care use in terms of costs. Indirect costs outside the healthcare sector are costs incurred outside the scope of the formal healthcare system arising as a secondary effect of the intervention, such as productivity costs due to absence or reduced efficiency during paid or unpaid work. The friction cost method will be used for the calculation of costs due to production losses.

* Effects will be measured in QALYs, which constitute a combination of quality of life and length of life. Quality of life will be measured in utilities. Utilities express quality of life on a scale from 0 (death) to 1 (perfect health). Utilities can be derived from the SF-12 (see previous section).
To conduct the cost effectiveness analysis a cost-effectiveness model will be developed. This model will comprise two treatment arms, respectively SAE compared to splenectomy . The cost-effectiveness study will be conducted according to the most recent Dutch guidelines for pharmacoeconomic research (Zorg Instituut Nederland, Diemen). As such, the study will be performed from the societal perspective, which means that all costs and benefits should be considered, regardless of by whom the costs are borne or to whom the benefits

accrue. The base case time horizon in the study will be 15 years. Alternative time horizons may be used in scenario analyses.

Analytical modeling provides an alternative framework for economic evaluation and allows using different data sources. In case of small number of patients a modeling approach is the most appropriate method to assess cost-effectiveness. The health economic model will be based on a disease specific model that will be developed in close cooperation with the clinicians. A decision analytic framework will be used in the shape of a probabilistic Markov model comparing both interventions: SAE treatment with splenectomy. Disease progression will be described using transitions between *states*, where a subject can move between states or remain in the current state. A big advantage of using such a model is the flexibility of a model to adapt to new insights from clinic practice or information extracted from literature, datasets or expert opinion during the study. The model will be constructed with Microsoft Excel 2010.

Study description

Background summary

Morbidity and mortality are the most commonly used outcome parameters in the literature on trauma care. However, most patients will survive their trauma and depending on the severity of the trauma, they will be limited in daily life, both physically and mentally. Multiple studies has shown psychological complaints and decreased quality of life (QOL) in severely injured patients. [1-3] These factors have a major social and economic impact because it often involves young patients, who frequently become unsuitable to return to work, to reintegrate back into society or to retrieve their previous activity level. Despite that QOL is an important factor, it is still not widely used in trauma care studies.

In splenic injury after blunt abdominal trauma much is known about morbidity

and mortality, but still very little in terms of QOL. The spleen is one of the most frequently injured organ after blunt abdominal trauma. [4] Internal bleeding caused by abdominal organ injury is one of the main causes of death after trauma, and a missed splenic rupture is the most common cause of preventable death in trauma patients. [5,6]
Presently, the standard of care in hemodynamically stable patients is nonoperative management (NOM) involving close observation of the patient, with success rates up to 90%. [4] Angiography and splenic artery embolization (SAE) can be used as a supplement to NOM when necessary. The success rate of SAE ranges from 73% to 100% with an overall success rate of NOM combined with SAE from 86% to 100% (most studies reporting success rates greater than 90%). [7]
There is still much unknown about splenic function after SAE, but there seems to be a link between splenic volume and immunologic status of the patient. Preservation of splenic function is one of the biggest advantages of NOM and SAE. Avoiding post-splenectomy complications such as sepsis and thrombocytosis and potentially preventing a lifetime risk of invasive infections. [8,9] In other words, avoiding factors with major impact on quality of life.
In all three therapies (NOM, SAE and surgery) minor and major complications may occur. Patients treated with SAE have a risk of developing splenic infarction, abscesses or cysts, with distal embolization having a significantly higher association with major complications compared to proximal embolization. [10]
A recent study suggests that there are prognostic factors for failure of NOM in the treatment of adults with blunt splenic injury. Strong evidence exists for: age of 40 years or above, Injury Severity Score (ISS) of 25 or greater and American Association for the Surgery of Trauma (AAST) splenic injury grade of 3 or greater. [11] Failure of therapy leads to more interventions, longer hospital stay and higher mortality; resulting in decreased QOL and increased costs.

There is a growing demand for a (national) guideline or protocol for clinical decision-making in traumatic splenic injuries. For that reason it is important to determine the optimal selection criteria for the appropriate management strategy. This can only be achieved by looking at the entire process surrounding a trauma patient.

The first aim of this project is to determine/compare the quality of life (QOL) and clinical outcome of patients after therapy (NOM, SAE, splenectomy) for traumatic splenic injury. First, this will be done with a retrospective group of patients and the results hereof will be extracted into the prospective part of the study.
The second aim is (I) to examine therapy-related complications, (II) to establish the necessity of additional therapies, (III) the assessment of splenic function related to splenic morphology (MR imaging) after treatment, and (IV) to find the prognostic factors for failure of non-operative management (NOM) in patients with splenic injuries.

Finally, with the acquired data from this study a patient-oriented protocol

will be provided for the management of traumatic splenic injury.

Study objective

The primary objective of this project is to demonstrate the equivalence of treatment of traumatic splenic injury with splenic artery embolization (SAE) compared to splenectomy and non-operative management (NOM) in terms of quality of life at different time points after treatment measured by WHOQOL-Bref and quality of life short-form-12 questionnaire.

Furthermore, the three treatments will be compared in terms of clinical outcomes, recovery related outcomes, quality of life outcomes and cost outcomes. Also imaging outcomes will be investigated in the SAE group, thereby identifying morphological (versus immunological) aspects of the spleen after endovascular treatment.

Finally, with the acquired data from this study a patient-oriented protocol will be provided for the management of traumatic splenic injury.

Specific questions:
1. Is SAE superior to splenectomy in terms of quality of life outcome at different time points after treatment?
2. How do NOM, SAE and splenectomy compare in terms of complications during treatment, need for re-intervention, hospital stay (days), return to daily activities (days)?
3. Is SAE cost-effective compared to splenectomy?
4. How does SAE affect imaging outcomes (splenic morpholical characteristics such as volume, necrosis, splenosis, califications or chronic infarction morphology) 1 month and 1 year after embolization?
5. Can we design a patient-oriented protocol for the treatment of traumatic splenic injury?
6. Is there a difference between proximal versus distal SAE? (immunologic/imaging)
7. What are the prognostic factors for failure of NOM?

Study design

A combination of a retrospective and a prospective multicentre cohort study will be conducted comparing non-operative management (NOM), splenic artery embolization (SAE) and splenectomy in patients with splenic injury after blunt abdominal trauma. This is supplemented with a systematic review of the literature that will be written according to the PRISMA criteria [13].
The literature search will consist of a staged process in order to retrieve all relevant articles. First, an extensive literature search will be done using PubMed, Cochrane, and PsycINFO and the publication date between January 2005 until the date of the search. The reference lists will be canned to identify

relevant articles that did not appear during the literature search. This search will result in an overview of the latest opinions with insight in state-of-the-art management of traumatic spleen injury.
The total duration of the project is 48 months.

Study burden and risks

Questionnaires quality of life (all patients):
If patients have an Internet connection, they will fill in the questionnaires online 1 week and 1, 3, 6 and 12 months after treatment. This will take approximately 15-30 minutes. If patients do not have an Internet connection, they will receive the questionnaires by post. This will possibly take more time.

MRI scan of the abdomen (only patients who have been treated with embolization of the splenic artery):
Patients will be called for a voluntary MRI abdomen in one of the participating hospitals one month and one year after treatment. Undergoing an MRI scan of the abdomen could be uncomfortable and may cause some physical and psychological discomfort. There are no known harmful or biological effects. Prior to the scan, contraindications for MRI will be excluded. Doing an MRI scan is necessary for this study to assess the spleen morphology after embolization of the splenic artery. The MRI examination will take approximately 45 minutes.

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 splenic injury after blunt abdominal trauma
- Treated with non-operative management, splenic artery embolization or splenectomy
- Treatment took place in the period from May 2016 to December 2018 at one of the eleven selected hospitals
- 18 years or older

Exclusion criteria

- Insufficient knowledge of the Dutch language
- Patiënts who died are (of course) excluded for questionnaires and follow-up MRI, not for clinical outcomes, Exclusion for MRI only:
- Patients treated with splenic artery embolization: patiënts who do not want to or are not able to undergo an MRI scan of the abdomen (for example pregnant women or other contraindications for MRI)
(Patients excluded for MRI still need to fill out the questionnaires. Also, their clinical outcomes will be processed in the database.)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-03-2017
Enrollment:	280
Type:	Actual

Ethics review

Approved WMO Date:	18-05-2016
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	01-07-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	19-10-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-09-2017
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	27-11-2017
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	07-12-2017
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-12-2017

Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	17-04-2018
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	20-01-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL54542.028.16