Intestinal Fatty Acid Binding Protein as a Marker for Increased Intra-Abdominal Pressure (I-Fabulous study)

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29639

Source
Nationaal Trial Register

Brief title
I-Fabulous

Health condition

Intra-abdominal hypertension and abdominal compartment syndrome

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center Rotterdam, Trauma Research Unit, Department of Surgery
Source(s) of monetary or material Support: Stichting Coolsingel (Rotterdam, the Netherlands)

Intervention

Outcome measures

Primary outcome

Intestinal Fatty Acid Binding Protein (I-FABP) level in urine

Secondary outcome

Claudin-3 level in urine and serum

I-FABP level in serum

Study description

Background summary

BACKGROUND

Intra-abdominal hypertension (IAH) and abdominal compartment syndrome (ACS) have detrimental effects on all organ systems and are associated with increased morbidity and mortality rates in critically ill patients admitted to an intensive care unit. Intra-bladder measurement of the intra-abdominal pressure (IAP) is currently the gold standard. However, it is not always feasible of reliable. Moreover, IAH is not always indicative of intestinal ischemia, which is an early and rapidly developing complication. Sensitive biomarkers for intestinal ischemia are needed in order to be able to intervene before damage becomes irreversible. Gut wall integrity loss, including breakdown of tight junctions, is an early event in intestinal damage. Intestinal Fatty Acid Binding Protein (I-FABP) is excreted into the urine and blood by damaged intestinal epithelial cells. Claudin-3 is excreted in urine following disruption of tight junctions.

AIM

The main aim of this study is to determine the relevance of I-FABP levels in urine as diagnostic tool for identifying patients at risk for intra-abdominal pressure-related problems. Secondary aims are to evaluate the same for serum I-FABP levels, to determine if Claudin-3 levels in urine (representing tight-junction disruption) correlate with IAP or I-FABP levels, and to determine if I-FABP and Claudin-3 levels can be used as prognostic indicator for intestinal ischemia-related morbidity.

STUDY DESIGN

Multi-center observational cohort study.

POPULATION

200 patients admitted to the Intensive Care Unit. Adult patients with at least two risk factors for IAH as defined by the World Society of the Abdominal Compartment Syndrome (WSACS) are eligible for enrolment. Patients in whom an intra-bladder IAP measurement is contra-indicated or impossible and patients with inflammatory bowel diseases that may affect I-FABP levels will be excluded.

METHOD

During the first 72 hours after enrolment, the IAP measurement will be repeated every six hours. At these time points, a urine and serum sample will be collected for measurement of I-FABP and Claudin-3 levels. Clinical outcome of patients during their stay at the intensive care unit will be monitored using the Sequential Organ Failure Assessment (SOFA) score.

OUTCOME MEASURES

I-FABP level in urine will serve as primary outcome measure.

I-FABP level in serum and Claudin-3 level in urine and serum will serve as secondary outcome measure.

Study objective

It is expected that the urinary and serum level of intestinal fatty acid binding protein (I-FABP) and the urinary level of Claudin-3 have prognostic relevance for early identification of patients at risk for intestinal ischemia-related morbidity or mortality

Study design

Every six hours from 0-72 hours after enrolment

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with at least two risk factors as agreed by the World Society of the Abdominal Compartment Syndrome (WSACS)

2. Age 18 or older, with no upper age limit

3. Signed informed consent by patient or proxy

Exclusion criteria

1. Patients with bladder trauma or hematuria in whom intra-bladder pressure measurement is contra-indicated

2. Patients in whom intra-bladder pressure measurements are not possible due to intraperitoneal adhesions, bladder oppressive pelvic hematoma, abdominal packs in situ, or previous bladder removal

3. Patients with inflammatory bowel disease that may affect I-FABP levels, such as Crohn's disease or ulcerative colitis

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-04-2011
Enrollment:	200
Type:	Actual

Ethics review

Positive opinion

Date:	24-06-2014
Application type:	First submission

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
NTR-new	NL4134
NTR-old	NTR4638
Other	: MEC-2011-016

Study results

Summary results

Strang SG, Van Waes OJF, Van der Hoven B, Ali S, Verhofstad MHJ, Pickkers P, Van Lieshout EMM. Intestinal fatty acid binding protein as a marker for intra-abdominal pressure-related complications in patients admitted to the intensive care unit; study protocol for a prospective cohort study (I-Fabulous study). Scand J Trauma Resusc Emerg Med. 2015 Jan 16;23(1):6.