Trauma and gut wall integrity.

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22240

Bron
NTR

Aandoening

multi-trauma, gut wall integrity

ongevalsletsel, darmwand integriteit

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Serum I-FABP, L-FABP and urine Claudin 3 as measures for gut wall integrity.

Toelichting onderzoek

Achtergrond van het onderzoek

Critical care complications such as multi organ failure replace hemorrhage as a major cause of trauma-related death after this initial period. Mortality rates in trauma are therefore for a large extent due to complications in organ systems not necessarily affected by the primary trauma. Severely injured patients are at risk for the development of systemic inflammatory response syndrome (SIRS). Approximately 30% of patients admitted to a level I trauma center will develop SIRS.

The subsequent development of multiple organ failure (MOF) results from the excessive production of inflammatory mediators like cytokines, chemokines and complement as well as derangement of the regulation of the innate and adaptive immune responses. A compromised hepatosplanchnic bloodflow has been postulated to play a central role in the transition of SIRS into MOF. Damage to the liver or the intestine due to a reduced blood flow might cause a release of constitutive hepatic and intestinal proteins in the systemic circulation. These proteins can act as “danger signals” and subsequently (further) activate the already activated immune system, which contributes to the development of SIRS. Preliminary data suggest the early presence of intestinal epithelial cell damage in trauma patients. Recognition of trauma patients with possible gut integrity loss who are therefore possible at increased risk of developing SIRS and subsequent MOF, is important.

Fatty Acid Binding Proteins (FABP) are proteins involved in the regulation of cellular lipid balance. While Intestinal-FABP (I-FABP) is solely present in mature enterocytes and appears immediately in the serum when the cell membrane integrity is compromised, Liver-FABP (L-FABP) mainly is present in the liver. Both have been determined to be accurate markers for ischemia-reperfusion induced damage in both animal models and patients. The same holds true for urine Claudin 3 levels, a marker for damage to the intestinal epithelial tight junctions and thus intestinal barrier function.
Early data suggests that the extent of intestinal damage (as measured by I-FABP levels and/or Claudin 3 levels) is associated with the presence of shock and injury severity in trauma patients. Higher FABP levels might also be an indicator of intra-abdominal injury, and thus an important adjunct to other investigations such as ultrasound or CT-scan, with their well known limitations.

This study sets out to investigate the clinically important questions whether I/L-FABPs and Claudin levels can be used as a diagnostic tool for the presence of severe intra-abdominal injury and predictive for the development of SIRS.

Doel van het onderzoek

We therefore hypothesize that FABP/Claudin levels may be used as a diagnostic tool for the identification of intra-abdominal injury necessitating surgery and as a prognostic marker for the development of SIRS/MOF (and morbidity and mortality) in trauma patients.
Finally we hypothesize that that-FABP/L-FABP and Claudin-3 levels are associated with the severity of the inflammatory and metabolic response on the biochemical level as measured by the cytokines TNFa, IL6, IL10 on one hand and lactate, base excess and PT/INR on the other, as the inflammatory response develops in time.

Onderzoeksopzet

1, 3, 6, 9 and 12 hours post trauma. Afterwards daily.

Onderzoeksproduct en/of interventie

Observational study so no interventions. Serum and blood will be collected every 3 hours for 12 hours post injury, afterwards daily to investigate the development of gut wall integrity loss in time.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. > 18 years;

2. Traumatic injury;

3. Admission to shock room of a level 1 trauma center.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

<18 years.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2010
Aantal proefpersonen:	600
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2094
NTR-old	NTR2211
Ander register	METC UMGC : 2010.010
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A