Near-Infrared Imaging for Perfusion Assessment of Traumatic Soft Tissue and Skeletal Injuries

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Soft tissue therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON53249

Source
ToetsingOnline

Brief title
IMPACT

Condition

- Soft tissue therapeutic procedures

Synonym
blood flow in soft tissue and bone, Musculoskeletal perfusion

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Niet;onderzoekers worden niet betaald

Intervention

Keyword: Fluorescence imaging, Indocyanine green, Perfusion, Traumatic injuries

Outcome measures

Primary outcome

The main endpoint of this study is an adequate time-intensity curve extracted from selected regions of interest. Adequate curves are defined as reproducible curves with accurate representation of the perfusion status. An adequate curve is characterized by a recognisable in- and outflow pattern representing the bloodflow in the tissue.

Secondary outcome

As secondary study parameters quantified perfusion parameters will be extracted from the time-intensity curves. The parameters extracted include:

• Maximum intensity (Imax)

• Time till maximum intensity (Tmax),

• The ingress rate

• The absolute slope

• The normalized slope

• Area under the curve at 30, 60 and 120 seconds

Perfusion parameters will be evaluated for their correlation with:

• Occurrence of necrotic tissue after initial debridement.

• Number of additional debridement procedures after initial debridement due to the occurrence of necrotic tissue.

• The occurrence of wound infection within 30 days after procedure. Infection

defined as a red, swollen and painful area that is warm and tender to touch, possibly in combination with fever/chills, purulent effusion, positive cultures or increased infection parameters.

• The occurrence of a fracture related infection as defined by Metsemakers et al.14

• Length of hospital stay.

• Number of readmissions within 30 days associated with complications of primary problem (infection, necrosis, death).

Study description

Background summary

In 2020 71.623 Dutch patients were acutely admitted to hospitals due to sustained traumatic injuries. 7% of the injuries related to open wounds and 44% to fractures. The majority of traumatic musculoskeletal injuries needs to be diagnosed and treated as soon as possible to lower the risk of infections and to minimize adverse outcome, such as necrosis and/or osteomyelitis. To date, intraoperative assessment of tissue and bone viability is predominantly subjective, resulting in a variation in thoroughness of debridement. If not all necrotic tissue is removed, suboptimal healing occurs, which serves as a potential food source for bacteria. In addition, inadequate initial resection leads to multiple debridement interventions, leading to prolonged hospitalization or readmission with consequently high direct medical costs. Since tissue necrosis is an ongoing process, radical resection of avital tissue during the initial procedure is not always possible. The surgeon's visual estimation is not optimal to predict the final amount of debridement. After maximal debridement, antibiotic treatment and coverage of open wounds, the incidence of infection can rise to 27%. Compromised perfusion is at the centre of this problem. An adequate blood supply is crucial for tissue viability and infection clearance. Near-Infrared Fluorescence (NIRF) imaging with Indocyanine Green (ICG) has already shown its potential in effective real-time assessment of intra-operative tissue perfusion and the early prediction of future necrosis in multiple studies. This technique could potentially be a relevant contribution in adequately treating soft tissue and skeletal injuries by creating an improved distinction between viable and non-viable tissue, based on perfusion indices. However to date, the feasibility to quantify this technique

in posttraumatic tissue has not been successfully evaluated.

Study objective

The primary objective of this study is the feasibility of assessing the quantified perfusion status of patients with traumatic soft tissue and/or skeletal injuries using NIRF imaging with ICG. Feasibility implies reproducibility of the measurements with quantifiable differences in perfusion patterns that can be correlated to the clinical outcome of adequate and inadequate perfusion, such as the occurrence of necrosis.

Study design

The study is a prospective observational multicentre pilot study. All included patients will undergo a perfusion assessment using ICG NIR fluorescence imaging. Perfusion assessment will not affect treatment of patients.

Study burden and risks

The study will pose no burden and minimal risk for the patients. For the ICG NIR fluorescence imaging measurement, an intravenous bolus of ICG will be administered. ICG is a drug approved by the FDA and has been widely used for assessment of perfusion in other medical fields. ICG has a very low toxicity.

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

• Age >= 18 years
• Diagnosed with one or more of the following injuries:
o Crush injury
o Open deglovement
o Open fracture(s) (Gustilo 3, -A, -B & -C)
o Non-union tibia/clavicula/ulna/humerus/rib
o Fracture related infection
• Indication for surgical intervention

Exclusion criteria

• Hemodynamically unstable due to severe blood loss
• Allergic or hypersensitive to iodine/crustaceans/shellfish
• Diagnosed with endocrine thyroid disorders (hypo/hyperthyroidism)
• Pregnancy
• Diagnosed with impaired renal function eGFR <30 L/min/1.73m2
• Diagnosed with severely disturbed hepatic enzymes/liver failure

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-02-2024
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	24-08-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL84014.058.23