Monitoring of tissue perfusion during reconstructive free flap surgery

No registrations found.

| Ethical review | Positive opinion |
|-----------------------|----------------------------|
| Status | Pending |
| Health condition type | - |
| Study type | Observational non invasive |

Summary

ID

NL-OMON29325

Source Nationaal Trial Register

Brief title MISSION study

Health condition

Defects caused by oncological resection or trauma.

Sponsors and support

Primary sponsor: none Source(s) of monetary or material Support: UMCG

Intervention

Outcome measures

Primary outcome

The main study parameter will be the ICG-derived fluorescence intensities during pre-, perand post-operatively NIRF angiography. In addition, the other main study parameters are the HSI oxygenation values and thermal imaging skin temperature values observed during postoperative evaluation of the flap.

Secondary outcome

Secondary paramters are the correlation between observerd fluorescence intensities, oxygenation values and local skin temperature with conventional diagnostic techniques and clinical outcomes.

Study description

Background summary

Adequate flap perfusion is crucial for reconstructive surgery success rates in order to restore function and normal appearance. Peri-operative feedback on flap design and postoperative monitoring of flap viability is known to be challenging, with limited accurate diagnostic imaging modalities available. Near-infrared fluorescence (NIRF) angiography with indocyanine green as dye that can visualize the cutaneous blood flow of the flap. In addition, post-operative flap viability can be determined with tissue perfusion measurement with techniques such as hyperspectral imaging and thermal imaging. In this study we want to determine the added value of NIRF angiography for peri-operative evaluation of flap design and free flap perfusion and subsequently the added value of hyperspectral imaging and thermal imaging for monitoring of free flap perfusion after reconstructive surgery.

Study objective

We hypothesize that NIRF angiography has added value for peri-operative evulation of flap design and free flap perfusion and subsequently we hypothesize that hyperspectral imaging and thermal imaging have added value for monitoring free flap perfusion after reconstructive surgery

Study design

Pre operatively , several times intraoperatively and twice daily post operatively untill discharge and once during post-op follow-up appointment.

Intervention

There will be no interventions in this study, it is an observational study

Contacts

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Eligibility criteria

Inclusion criteria

Patients \geq 18 years old that are fit for surgery and scheduled to undergo free flap surgery for reconstruction of a defect caused by oncological resection or trauma will be included.

Exclusion criteria

Pregnancy or lactation; Participation in another fluorescence imaging study investigating ICG or a targeted optical imaging agent in the near-infrared fluorescence imaging wavelength (>650 nm) within one month prior to enrollment; A known severe hepatic or renal insufficiency; A history of hyperthyroidism; An autonomous thyroid adenoma; A history of allergic reactions to ICG or Iodine

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

| Recruitment status: | Pending |
|---------------------------|-------------|
| Start date (anticipated): | 02-03-2020 |
| Enrollment: | 20 |
| Туре: | Anticipated |

IPD sharing statement

Plan to share IPD: No

Ethics review

| Positive opinion | |
|-------------------|------------------|
| Date: | 11-02-2020 |
| 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 | NL8380 |
| Other | METC UMCG : METC2019457 |

Study results