Monitoring of tissue perfusion during reconstructive free flap surgery

Gepubliceerd: 11-02-2020 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29325

Bron
Nationaal Trial Register

Verkorte titel
MISSION study

Aandoening

Defects caused by oncological resection or trauma.

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: UMCG

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter will be the ICG-derived fluorescence intensities during pre-, per- and 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients ≥ 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
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:	02-03-2020
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	11-02-2020
Soort:	Eerste indiening

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	NL8380
Ander register	METC UMCG : METC2019457

Resultaten