Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for the treatment of trauma patients in distress from torso hemorrhage; a prospective follow-up study in a Dutch level I trauma center

Gepubliceerd: 13-07-2020 Laatst bijgewerkt: 18-08-2022

REBOA is expected to be successful in raising the central systolic blood pressure in trauma patients suffering from major truncal or junctional hemorrhage.

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

Samenvatting

ID

NL-OMON25387

Bron
Nationaal Trial Register

Verkorte titel
REBOA-ProFo

Aandoening

Trauma patients who are treated using REBOA for presumed traumatic life-threatening hemorrhage or traumatic cardiac arrest.

Ondersteuning

Primaire sponsor: Erasmus MC, University Medical Center Rotterdam, Trauma Research Unit Department of Surgery
Overige ondersteuning: Ministry of Defense, SZVK

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Whether REBOA was successful

Toelichting onderzoek

Achtergrond van het onderzoek

BACKGROUND
Controlling non-compressible torso hemorrhage (NCTH) is one of the biggest challenges trauma surgeons face today. Over the last years the use of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) in the management of traumatic NCTH is rising. However, it is not yet widely adopted in Dutch trauma centers. REBOA is an endovascular technique to temporarily obstruct blood flow to the distal circulation using a compliant balloon catheter in trauma patients suffering from major truncal or junctional bleeding. REBOA is considered as a less invasive alternative to open aortic cross clamping for certain indications. It has recently been introduced in Erasmus MC Rotterdam as adjunct in the management of hemorrhagic trauma patients.

AIM
The primary aim of this study is to evaluate the success rate of REBOA cases in a Dutch level I trauma center.

The secondary aims are:
1) To evaluate the time needed to obtain hemorrhage control with REBOA;
2) To evaluate the complications related to the use of REBOA;
3) To evaluate the survival rate in the trauma patients treated using REBOA;
4) To make a careful evaluation of every step in the REBOA procedure, the circumstances under which it is performed and its effect; and
5) To increase the knowledge of the patient demographics, injury characteristics, clinical parameters, the deployed resources and interventions, and hospital course of trauma patients treated using REBOA.

STUDY DESIGN
Prospective observational study

POPULATION
Trauma patients who are treated using REBOA.

INTERVENTION

No interventions will be used.

ENDPOINTS
The primary outcome measure is whether REBOA was successful. The secondary outcome measures are time needed to obtain hemorrhage control with REBOA, complications, survival, REBOA procedure data, patient demographics, injury characteristics, field data, admission data, and hospital course of patients treated using REBOA.

RECRUITING COUNTRIES
The Netherlands.

Doel van het onderzoek

REBOA is expected to be successful in raising the central systolic blood pressure in trauma patients suffering from major truncal or junctional hemorrhage.

Onderzoeksopzet

During hospital admission and 30 days after trauma or until hospital discharge if hospital stay exceeds the 30-day follow-up period.

Onderzoeksproduct en/of interventie

Not applicable

Contactpersonen

Publiek

Erasmus MC, University Medical Center Rotterdam
R. Hoencamp

+31107031050

Wetenschappelijk

Erasmus MC, University Medical Center Rotterdam
R. Hoencamp

+31107031050

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Presented to Erasmus MC because of a physical trauma
2. Treatment attempted using REBOA (whether or not successful) for presumed traumatic life-threatening hemorrhage or traumatic cardiac arrest.
3. Provision of deferred informed consent (IC) by patient or proxy

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

No exclusion criteria apply.

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 gestart
(Verwachte) startdatum:	08-07-2020
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	13-07-2020
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	NL8776
Ander register	METC Erasmus MC : MEC- 2020-0517

Resultaten