FABRA-study.

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The presence of close family members of the patient, who are informed about the exclusion of reversible confounders (e.g. metabolic disturbances, hypothermia or intoxication) and are present at the examinations that are necessary for the...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21921

Bron
Nationaal Trial Register

Verkorte titel
FABRA

Aandoening

brain death
organ donation
family refusal
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hersendood
orgaandonatie
familieweigering

Ondersteuning

Primaire sponsor: Erasmus MC Intensive Care
Rotterdam
Chair: Prof. dr. J. Bakker
Overige ondersteuning: sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The rate of consent or refusal for organ donation by close family members of a potential brain death patient,
who were present during brain death determination.

Toelichting onderzoek

Achtergrond van het onderzoek

While organs like kidneys, liver or lungs can be procured from a non-heart beating organ donor and a kidney or a part of a liver can be donated by a living donor, the heart can only be obtained from a brain death donor. Besides that, a mechanical ventilated brain death donor with isolated brain damage is the “ideal” multi-organ donor. Around 85% of the patients with a confirmed diagnosis of brain death were admitted at the ICU after a traumatic brain injury or a subarachnoid hemorrhage (SAH). However brain death is since 1970 an increasingly rare outcome of this disorders in the Netherlands.

The Dutch Coordination Group Organ Donation (CGOD) stated that a transition to a Active Donor Registration system (ADR) is an important step to increase the absolute number of organ donations after death. This is probably too much based on the presumption that a large and hitherto unused potential exists. Although a beneficial effect of the ADR would be real in case of the non-heart-beating donors, it is very unlikely that this would be the same for the heart-beating donors. As a result of the significant decline in the number of road traffic accidents (RTA) and RTA-related deaths due to traumatic brain injury (TBI) since 1970 and the effectiveness of preventive measures resulting in a decline in the incidence of SAH, like discouraging smoking and early detection of hypertension, an increase of brain death organ donors is not expected. Looking at incidence and especially mortality rates of TBI and SAH, an rough estimation of the potential can be made. An important measure to increase the absolute number of conducted organ donations from brain dead donors can result from a decline in the number of family-refusals for organ donation. In the Dutch Master plan organ donation report (2008) a refusal rate for non-registered donors, a best estimate of 51-53% is described. The exact figure is however unknown. How many potential organ donors, as a result of family refusal, will not end as effectuated organ donors is unknown. It is however generally determined that relatives play a central role in whether or not an organdonation can be carried out. For family members the conformation of brain death, and the question of organ donation are conceptual and emotional inextricably linked with each other. Family members of patients “recognize” death by the absence of medical intervention, which is confusing when a dead patient is mechanically ventilated, medicaments are administered and his or her heart is still beating. It appears to be especially difficult to understand the difference of ‘spontaneous breathing’ and 'to be mechanically ventilated'. Existing breathing appears conceptual and emotional to be strongly associated with “life”

Doel van het onderzoek

The presence of close family members of the patient, who are informed about the exclusion of reversible
confounders (e.g. metabolic disturbances, hypothermia or intoxication) and are present at the examinations
that are necessary for the determination of brain death, shall give a better understanding of the concept of
brain death and can possibly lead to a higher consent rate for organ donation.

Onderzoeksopzet

We ask for organ donation directly after participation of the trial. After three weeks and six months we offer the family members a questionnaire about their expericiences during and after the examinations for brain death determination.

Onderzoeksproduct en/of interventie

To offer family members the opportunity to experience and observe the examinations that are essential for the
determination of brain death (with exception of the electroencephalography).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. A suspicion of a brain death patient on a intensive care unit of one of the participating hospitals (patient satifies the preliminary conditions of the brain death protocol. Glasgow coma scale of 3, more than 1 absent brainstem reflex and mechanical ventilation);

2. Qualifies for postmortal organ donation with respect to age and the medical condition;

3. Direct relatives are present on the ICu (18 years or older).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patient does not satisfy the preliminary conditions as for postmortal hearbeating organ donation;

2. Does not qualify for postmortal organ donation medically or with respect to age;

3. No direct relatives of the patient present on the ICU;

4. Refusal of the patient for organ donation as declared in the "Donorregister" by the patient.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2009
Aantal proefpersonen:	240
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-06-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35712
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1777
NTR-old	NTR1887
CCMO	NL26926.078.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35712

Resultaten

Samenvatting resultaten
N/A