Family presence during brain death determination

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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 a part of the examinations that are necessary for the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35712

Source
ToetsingOnline

Brief title
FABRA

Condition

- Other condition

Synonym
n.v.t.

Health condition

ernstige irreversibele neurologische schade leidend tot hersendood

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Het ministerie van VWS

Intervention

Keyword: brain death, family refusal, organ donation

Outcome measures

Primary outcome

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.

Secondary outcome

Understanding of the concept of brain death by family members of patients with severe irreversible neurological damage.

Study description

Background summary

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*

Study objective

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 a part of 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

Study design

A multi-centre intervention study. There is a mix of academic and larger secondary hospitals.

Intervention

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).

Study burden and risks

The risk and burden for the patient is nil. There are no additional interventon

for the study. The burden for the family seems larger because the family is actively involved in the entire donation process, which ultimately, should result in the determination of brain death. We hope that through this participation the mourning process for the family for such a far-reaching event will be better. So, the net burden for the family will eventually be lower.

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

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)

Exclusion criteria

1. Patient does not satisfy the preliminary conditions as for postmortal hearbeating organ donation.
2. Refusal of the patient for organ donation as declared in the "Donorregister" by the patient
3. Insufficient understanding of the Dutch language

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-04-2010
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	02-07-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-04-2010
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21921
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL26926.078.09
Other	TC-1887
OMON	NL-OMON21921