

# FABRA-study.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON21921

### Source

Nationaal Trial Register

### Brief title

FABRA

### Health condition

brain death  
organ donation  
family refusal  
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hersendood  
orgaandonatie  
familieweigering

## Sponsors and support

**Primary sponsor:** Erasmus MC Intensive Care  
Rotterdam

Chair: Prof. dr. J. Bakker

**Source(s) of monetary or material Support:** sponsor

## Intervention

## 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 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**

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 experiences during and after the examinations for brain death determination.

### **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).

## **Contacts**

### **Public**

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Intensive Care  
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Rotterdam 3000 CA  
The Netherlands  
0031-6-53837655

### **Scientific**

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Erasmus MC  
Intensive Care  
Room H 3.24  
Rotterdam 3000 CA  
The Netherlands

## Eligibility criteria

### Inclusion criteria

1. A suspicion of a brain death patient on a intensive care unit of one of the participating hospitals (patient satisfies 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. 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.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

## Recruitment

NL  
Recruitment status: Pending  
Start date (anticipated): 01-09-2009  
Enrollment: 240  
Type: Anticipated

## Ethics review

Positive opinion  
Date: 29-06-2009  
Application type: First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 35712  
Bron: ToetsingOnline  
Titel:

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

No registrations found.

## In other registers

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

## Study results

## **Summary results**

N/A