

# CONSULT 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-OMON28443

### Source

Nationaal Trial Register

### Health condition

Impact of prognostic models of mortality in clinical practice.

## Sponsors and support

**Primary sponsor:** Afdeling Klinische Informatiekunde, Academisch Medisch Centrum, Amsterdam

**Source(s) of monetary or material Support:** Afdeling Klinische Informatiekunde, Academisch Medisch Centrum, Amsterdam

## Intervention

## Outcome measures

### Primary outcome

1. Perception of mortality risk;
2. (Un)certainty about the decision to withdraw treatment.

### Secondary outcome

1. Perceived usefulness of the prognostic information provided by the model;

2. Percentage of planned versus unplanned deaths in the ICU.

## Study description

### Background summary

Aim:

To assess the impact of prognostic information provision on their perceptions of individual mortality risks and their decisions regarding provision of life support to these patients.

Due to ethical considerations this study only concerns non-survivors and is conducted in only one centre, which allows us to control the study in a small, in-house environment.

For a period of at least four weeks, one of our intensivists will daily check which patients died in the last 24 hours, whether treatment was withdrawn in this patient and who were the attending physicians. For each patient in whom treatment is withdrawn, one of our researchers will calculate his/her survival chance based on an earlier developed prognostic model. The attending team will then receive a link to an online questionnaire prepared by this researcher which contains: 1) A set of demographical questions, 2) A set of 3 questions concerning the physicians' perception of mortality risk in this patient and his/her certainty about the decision they made, 3) the survival chance of this patient together with a confidence interval, and 4) a repetition of the same 3 questions described in point 2. The questionnaire will not contain any patient information to guarantee the patients' privacy. All observed patients will be followed until death or hospital discharge.

The main research question is:

Does prognostic information regarding a patient's probability of survival influence:

1. Clinicians' perceptions of mortality risks?
2. Clinicians' uncertainty regarding their decision?

### Study objective

We hypothesize that providing additional objective prognostic information regarding a patient's chance of survival based on a mathematical prognostic model will influence the

physician's perception of mortality risk and their (un)certainly about the decision they make to withdraw ICU treatment.

## **Study design**

Daily (in case of a death after withdrawal of ICU treatment).

## **Intervention**

The attending physicians of patients who died after withdrawal of ICU treatment receive a questionnaire in which questions are asked regarding:

1. Their perception of mortality risk (if treatment had been continued);
2. Their (un)certainly about their decision.

Next a survival chance will be provided based on an objective prognostic model. The same set of questions will be asked again to measure the effect of the model on the physicians' perception of mortality risk and (un)certainly about their decision.

## **Contacts**

### **Public**

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## Eligibility criteria

### Inclusion criteria

Patients who died during ICU stay after withdrawal of ICU treatment.

### Exclusion criteria

N/A

## Study design

### Design

|                     |                         |
|---------------------|-------------------------|
| Study type:         | Interventional          |
| Intervention model: | Parallel                |
| Allocation:         | Non controlled trial    |
| Masking:            | Open (masking not used) |
| Control:            | N/A , unknown           |

### Recruitment

|                           |             |
|---------------------------|-------------|
| NL                        |             |
| Recruitment status:       | Pending     |
| Start date (anticipated): | 01-09-2012  |
| Enrollment:               | 25          |
| Type:                     | Anticipated |

## Ethics review

|                   |                  |
|-------------------|------------------|
| Positive opinion  |                  |
| Date:             | 21-08-2012       |
| Application type: | First submission |

## Study registrations

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

No registrations found.

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

No registrations found.

### In other registers

| Register | ID                                  |
|----------|-------------------------------------|
| NTR-new  | NL3438                              |
| NTR-old  | NTR3589                             |
| Other    | METC AMC : W12_178                  |
| ISRCTN   | ISRCTN wordt niet meer aangevraagd. |

## Study results

### Summary results

N/A