DIST Standard Operation Procedures

Information provision in the acute phase

DIST information meeting	**Version No: 1.0**	**Valid as of** 06-12-2022

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1. General

Dutch Intracerebral hemorrhage Surgery Trial (DIST) uses deferred informed consent, also known as *deferred consent*. This document is intended to provide tools for the conversation to be held with the patient and/or his legal representative in the acute phase:

1) by the healthcare provider in a general hospital for referral to *possible participation* in the DIST at a neurosurgical center;
2) by the healthcare provider in the neurosurgical center who aims to include the patient.

For more information about obtaining deferred informed consent in the subacute phase, please refer to **SOP: Information provision and deferred informed consent in the subacute phase**.

2. Information provided at the general hospital (referring center)

Guideline text for healthcare provider in general hospital prior to transfer to a neurosurgical center

"We want to transfer you to another hospital with dedicated experience in the treatment of patients with a brain hemorrhage. You will be transferred by ambulance to the emergency room of the other hospital. There, a team of doctors and nurses will assess whether they have additional treatment options for you. Depending on the assessment in the other hospital, it will be determined whether you will be admitted and treated there, or whether you will be transferred back to our hospital."

3. Information provided at the neurosurgical center

3.1. Inventory of treatment preferences

If a patient meets the inclusion and exclusion criteria for participation in DIST, it is important to discuss the patient's treatment preferences and pre-pronounced treatment restrictions prior to randomization. If a restrictive policy has been expressed by the patient and/or his legal representative, of which it is plausible that the patient would no longer wished to be operated, the patient should not be randomized (to selectively prevent drop-outs in the surgery group after randomization).

Guideline text for inventory of treatment wishes prior to randomization

"Patients with a cerebral hemorrhage sometimes require intensive treatment. It is therefore good to talk about your treatment preferences and boundaries in advance to deciding on the potential treatment possibilities. Have you ever thought about what you would still want and what you might not want anymore? Think, for example, of resuscitation in the event of cardiac arrest, admission to intensive care or surgical treatments."

3.2. Information per research group

In case of allocation to the control group, the standard admission interview for patients with an intracerebral hemorrhage (ICH) will be conducted. A general explanation of the standard medical care for ICH will suffice.

In case of allocation to the surgery group, verbal permission is requested for the surgical procedure to be performed. A general explanation of the surgical procedure, including the risk of complications, is sufficient. Explanation that the procedure is being carried out in the context of a clinical trial is omitted in acute phase but will be extensively explained in the context of the deferred consent procedure.

Guideline text in randomization into the surgery group (minimally invasive endoscopy-guided surgery)

"We have consulted with the team, and we propose an operation. During this operation, the neurosurgeon removes as much blood as possible. Our aim is to increase your chance of survival and independence after this brain hemorrhage. However, it is difficult to predict what effect the operation will be. The operation is performed under general anesthesia by means of keyhole surgery, which means that a small hole will be made in the skull. An endoscope, which is a small device with a camera, is

inserted through this hole into the area of the brain hemorrhage. This device can remove the brain hemorrhage with a special vibrating and suction device, without further damaging the brain tissue. Sometimes a drain is also placed to drain the cerebrospinal fluid to reduce the pressure in the brain. After the operation, you will be admitted and your blood pressure will be checked and treated if necessary, and you will receive treatment aimed at preventing complications and promoting recovery. Despite the potential positive effects of surgery, any surgery carries a risk of complications. The risks of this operation are the small chance of an infection, an epileptic seizure, leakage of cerebrospinal fluid from the surgical wound, and a new brain hemorrhage resulting in a second operation. In the event that a drain is also placed, the risk of infection is slightly greater."

4. RELATED DOCUMENTS

- **SOP: Information provision and deferred informed consent in the subacute phase**

5. DOCUMENT HISTORY

Version	Description of change	Date of implementation
1.0	First version	06-12-2022