Information letter for next of kin about participation in medical scientific research

A study on the effect of carotid artery stenting during endovascular treatment of acute ischemic stroke

Official English title: CASES: Stenting a carotid stenosis during endovascular thrombectomy compared to an endovascular thrombectomy with delayed treatment of a carotid stenosis in patients with an acute ischemic stroke caused by a proximal intracranial occlusion.

Dear Sir/Madam,

You are receiving this letter because your partner/family member (from now on: your loved one) has suffered a acute ischemic stroke and unfortunately has passed away. First, we offer you our heartfelt condolences for your loss. We are very sorry to have to bother you with this letter during this difficult period, but we would like to inform you about the participation of your loved one in a medical-scientific study during hospitalization due to an acute ischemic stroke.

The study into the effect of placing a stent in the carotid artery was set up by the UMCG in collaboration with Erasmus MC. The study is being conducted in in multiple centers in the Netherlands and Belgium. A total of 600 patients will participate in the study. The aim of this study is to find out whether treating the carotid artery during catheter treatment results in better recovery compared to deferred treatment. At the moment, that is still uncertain.

An acute ischemic stroke occurs when a blood vessel in the brain is blocked by a clot and a part of the brain therefore does not receive blood and is damaged. The symptoms that can arise from this condition include paralysis, sensory disturbances, language problems and/or partial blindness. To increase the chances of recovery, patients are treated with catheter treatment through the groin (endovascular treatment) if possible. This is a procedure in which the doctor visualizes the blood vessels in the brain through the groin. This is done with a thin tube, a catheter. Through this endovascular treatment, the blood clot is removed from the artery. For this treatment, the sooner the procedure starts, the greater the chance of recovery.
About 1 in 3 treated people are able to function independently after a recovery period of 3 months.
In 1 in 5 treated people, the clot is caused by a severe stenosis in the carotid artery. A severe stenosis of the carotid artery gives a high risk of a new cerebral infarction in the first few weeks. Therefore, people with a carotid artery stenosis are often operated on within 2 weeks after the acute ischemic stroke to prevent another stroke. The carotid artery stenosis can also be relieved immediately during the endovascular treatment by placing a stent. A stent is a small tube with a mesh structure that can be placed in a blood vessel to correct the stenosis in the carotid artery. The advantages of stenting directly during endovascular treatment is that a patient only has to undergo one procedure and that the risk of a new ischemic stroke is immediately reduced. A possible disadvantage is that people must use two blood thinners for a longer period of time after stenting than when there is no stent placed. That is why we want to use this research to study whether the immediate stenting of a carotid artery stenosis at the time of endovascular treatment of an acute ischemic stroke works at least as well as delayed treatment of carotid artery stenosis.
For this study, all participants will be assigned to one of the following two treatment groups by lottery:

- Group 1: has immediately undergone a stenting of the carotid artery at the time of the endovascular treatment for acute ischemic stroke
- Group 2: has not undergone carotid artery stenting at the time of the endovascular treatment for acute ischemic stroke (control group, standard of care)

The division into treatment groups and undergoing the treatment has taken place before you or your loved one could give fully informed, written consent to participate in the scientific study. It was our intention not to ask permission to participate in the study at the acute stage, but to postpone it until a quieter time. The reasons for this were the severity of your loved one's symptoms upon entering the hospital and the importance of removing the clot as soon as possible and treating the cause. Furthermore, previous research shows that this treatment has a limited risk. The study, and the request for permission at a later stage, has been reviewed and approved by the Medical Ethics Review Committee of the Erasmus Medical Center Rotterdam.

In the case of your loved one, the treatment has not been able to prevent the death of your loved one. During the hospitalization, we were unable to inform your loved one or you about the study earlier and ask for written permission for further participation in the study. That is why we would like to inform you about this research.
The use of your relative's data is of great importance for future patients with an acute ischemic stroke. We will therefore use the data in the analysis of the study results of the entire group of participants.
If, after reading this letter, you still need further information, we are of course happy to answer your questions. You can contact one of the researchers below by phone or send an email to:
cases-trial@umcg.nl

Thank you for your time, and good luck.
Respectfully
Dr. J.H. van Tuijl, neurologist, Elisabeth-TweeSteden Hospital Tilburg
Dr. G.J. Kortman, interventional radiologist, Elisabeth-TweeSteden Hospital Tilburg

Also on behalf of the research team of the CASES trial:
Drs T. van Elk, neurology, physician-researcher at UMC Groningen
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