Next of Kin information for PULSE-MI 2

Your relative (the study participant) has been admitted to the hospital because they have had an acute heart attack, which blocked one of their coronary arteries. They have therefore undergone a balloon angioplasty to open the artery. When a heart attack occurs, an inflammatory reaction develops in the affected area, which can increase damage to the heart muscle.

This research project investigates whether reducing this inflammatory reaction can decrease heart damage and improve survival. The project is conducted at several hospitals in Denmark and is led from the Department of Cardiology at Rigshospitalet by Dr. Jasmine Melissa Marquard, Dr. Ben Elezi, Associate professor Jacob Lønborg, and Professor Thomas Engstrøm.

Treatment in the Ambulance

On the way to the hospital, your relative received either the active study medication (steroid) or a placebo (saline). This was done before consent could be obtained because fast treatment for a heart attack is crucial to limit heart damage and increase the chance of survival.

Why You Are Receiving This Information

Your relative is seriously ill after an acute heart attack and may temporarily be unable to make a decision about participating in the research project. You are therefore being informed as the closest next of kin to consider whether your relative can temporarily participate until they are able to decide for themselves. You are entitled to take time to consider this and to receive verbal information about the study.

When your relative is sufficiently recovered, they will receive written and verbal information about the project and will be able to decide whether participation should continue and, if desired, sign a consent form. Your relative has the right to take time to decide and can withdraw consent at any time without affecting further treatment.

Participation in the project is voluntary, and neither your decision nor your relative’s decision will affect the treatment they would otherwise receive.

In principle, the information collected during the study will be stored and used. If you and/or your relative do not provide consent, you will be informed about your right to object to the use of data that has already been collected as part of the study.

Purpose of the Research Project

During an acute heart attack, a strong inflammatory response occurs, which can increase damage to the heart muscle. The extent of heart damage greatly affects the risk of heart failure and death after the heart attack. Current data show that 5–10% of patients die as a result of heart damage.

In a previous Danish study using the same type of medication, given at the same time (before balloon angioplasty), patients who received the medication had less acute heart muscle damage and signs of improved survival compared with those who received placebo. The results were promising, but the study was too small to change standard treatment based on this alone.

The purpose of PULSE-MI 2 is therefore to investigate, in a larger trial, whether a single early dose of anti-inflammatory medication (steroid), given before balloon angioplasty, can reduce mortality and improve long-term outcomes for patients with acute heart attack. The collected data may be crucial in determining how heart attacks are treated in the future—both in Denmark and internationally.

If your relative's data are later needed for research purposes other than those described here, the project will be submitted to a Research Ethics Committee. As a rule, new consent will be obtained unless the committee specifically determines that there is no risk or burden to your relative.

How the Study Works

The study is a randomized trial. This means your relative has been randomly assigned to receive either the active study medication (steroid) or placebo (saline).

The randomization is done by a computer program, so there is a 50% chance of receiving either treatment. The result of the randomization will be revealed at the end of the study. The study medication is given as a short infusion into a vein in the arm over about five minutes. Only this single dose is given.

Study Plan

A total of 5,204 patients with acute heart attack will participate. The project is expected to start in early 2026 and continue through 2036.

Possible Benefits of Participation

Your relative will receive the same standard treatment for heart attack, whether they participate in the study or not. There is no guarantee that your relative will personally benefit, but the project may provide important knowledge about whether this treatment can improve survival and reduce heart damage for future patients.

Side Effects, Risks, and Disadvantages

Balloon angioplasty of the coronary artery is a well-known and recommended treatment for a major heart attack. Risks and possible complications of the procedure are part of routine care and information.

The study medication is a steroid, which is used in other contexts such as chemotherapy, lung diseases, organ transplantation, and certain types of arthritis. Long-term use of steroids can cause side effects such as increased risk of infection, high blood pressure, high blood sugar, stomach ulcers, glaucoma, reduced wound healing, and skin bleeding. For a single, short infusion as in this study, the risk of these side effects is smaller but cannot be completely excluded.

In the previous Danish study using the same medication for heart attack patients, no more side effects were observed in the group receiving active medication compared with the placebo group. In this study, your relative will be closely monitored during and after the infusion. If doctors believe your relative cannot tolerate the treatment, the infusion will be stopped immediately, and any side effects will be treated.

There may be unknown risks. If your relative experiences new or worsening symptoms during the study, doctors will assess whether they may be related to the study treatment and inform you of any new developments. As a participant, your relative is covered by patient compensation.

Standard Treatment

Regardless of participation in the study, your relative will receive the hospital's usual care for heart attack, including balloon angioplasty, blood-thinning medication, and other heart medications as determined by their doctors.

Ending Participation

Your relative's participation may be ended if they cannot tolerate the treatment, if doctors decide that continued participation is no longer in the patient's best interest, or if your relative chooses to stop once able to make the decision themselves.

An independent safety committee monitors the study. If clear signs of benefit or unacceptable side effects are observed, the study may be stopped early.

Medical Records and Use of Data

To assess whether your relative can participate and to carry out the study, information will be collected from their medical records, including diseases, medications, blood tests, and clinical or imaging studies. Social and, if relevant, ethnic information may also be collected.

Medical history will be accessed at admission and approximately 1, 5, and 10 years later. These data will be used to evaluate the short- and long-term effects and safety of the treatment. Data may also be used for additional research, education, and publication within the scope of this project.

Information will be treated confidentially in accordance with the Danish Data Protection Act and GDPR. In the research database, your relative will be registered with an identification number; their name and personal identification number will not appear. Only the project's doctors, research assistants, and study nurses have access.

By giving consent, you also allow the Danish Medicines Agency, the sponsor, study investigators, and monitors to access medical records as needed for control and quality assurance. The study is approved by the Danish Research Ethics Committees (EU CT number: 2025-524320-21-00) and notified to the Danish Data Protection Agency.

Financial Information

The study is developed and led by doctors at the Department of Cardiology, Rigshospitalet. None of the involved doctors, staff, department, or Rigshospitalet have financial interests in the study or the medication used. The study is funded by the Danish Heart Foundation (DKK 8.8 million) and Health Donations (DKK 6 million). Your relative will not receive financial compensation for participation.

Publication of Results

The study will be registered at http://clinicaltrials.gov. Results will be published in scientific journals and presented at national and international conferences. Your relative will not be identifiable in these publications.

Your Rights

A general description of your relative's rights as a research participant can be found here: https://www.dvmk.dk/forsoegsperson/dine-rettigheder-som-forsogsperson-medicin

Under GDPR, you have the right to access the information processed about your relative and to have any errors corrected. You may also request access to the study protocol under the Danish Public Administration Act. To exercise your rights as next of kin, contact the study investigator.

More about your rights as next of kin: www.datatilsynet.dk. You also have the right to file a complaint with the Data Protection Agency if you are dissatisfied with the handling of your relative's data.

Questions and Contact

We hope that this information has given you a good understanding of what it means for your relative to participate in the research project and that you feel ready to support decision-making regarding their participation.

If you would like to know more about the research project, you are very welcome to contact one of the people listed below:

Project contacts:

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Study title

Danish: Binyrebarkhormon til patienter med akut blodprop i hjertet – PULSE-MI 2

English: Steroid treatment in patients with heart attack - PULSE-MI 2