

# Hodgkin's lymphoma: Benefit of stem cell transplantation with an unrelated donor unclear

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It remains an unresolved question whether adult patients with Hodgkin's lymphoma, a certain type of lymph node cancer, benefit from allogeneic stem cell transplantation (SCT) with an unrelated donor.

This is due to the fact that studies are lacking that compare this therapy with autologous transplantation or conventional chemotherapy without SCT. In addition, the few studies comparing SCT with an unrelated donor versus SCT with a related donor provide neither proof nor indications of an advantage. However, it cannot be inferred from the studies that both procedures are equivalent. Nevertheless, in IQWiG's opinion, under specific conditions it is justified to offer certain patients allogeneic SCT, including transplantation with an unrelated donor. This is the result of a final report published by the German Institute for Quality and Efficiency in Health Care (IQWiG) on 27 September.

## Relatively rare disease

[Hodgkin's lymphoma](#) is a relatively rare malignant disease of the haemopoietic system. About 2000 people are newly affected in Germany every year. For these patients, standard treatment comprises a combination of chemo- and [radiation therapy](#); about 80% of patients are cured in this way. However, in the remaining patients, tumour cells do not respond to treatment or patients experience a relapse after initially successful therapy. In certain cases, subsequent treatment with SCT is

therefore recommended.

In this procedure, the patient's affected bone marrow is first destroyed with high-dose chemotherapy (conditioning). Stem cells of a donor are then transplanted and settle in the [bone marrow](#). The procedure is called autologous SCT if the transplanted stem cells originate from the patients themselves. They are taken from the patient's own body before high-dose chemotherapy and then reinfused. If the transplant originates from a different donor, the procedure is called allogeneic SCT. In this context a distinction is made between related and unrelated donors.

In principle, SCT is an intervention fraught with risk, as there is quite a substantial risk of death resulting from conditioning, or of suffering other serious treatment-related complications. For example, donor cells may attack organs of the recipient (graft-versus-host disease).

## **Still an experimental procedure**

If the Hodgkin's lymphoma recurs, professional societies first recommend autologous SCT. The chances of curing the disease with this treatment are about 50%. In patients in whom the tumour recurs even after one or several autologous transplantations, allogeneic SCT can be considered as a treatment option under certain conditions. However, this procedure is still regarded as experimental. Between 1998 and 2008, a total of 167 patients with Hodgkin's lymphoma underwent allogeneic SCT in Germany; about half of them received a transplant from an unrelated donor.

The Federal Joint Committee (G-BA) commissioned IQWiG to assess allogeneic SCT with an unrelated donor. For this purpose, adult patients who underwent this procedure were to be compared with those who underwent autologous transplantation or chemotherapy without SCT. In addition, among other things, the benefits and harms were to be

compared between allogeneic SCT with an unrelated donor versus allogeneic SCT with a related donor.

## **Studies only available for one research question**

IQWiG could only find studies on the last research question. This was disappointing as the Institute had conducted a very broad literature search and had also included study types that are in principle of only limited informative value, such as registry data. Ultimately 8 studies (including 2 registry analyses) were available for the comparison between unrelated and related donors in allogeneic SCT.

It could not be clearly inferred from these studies which donor type offered the better prospects of success in patients with Hodgkin's lymphoma. Overall the studies were rather small and of poor quality and did not contain information on many aspects. This uncertainty also applies to adverse effects and complications. It is an essential issue that the studies did not allow conclusions as to whether the two procedures are equivalent.

## **Inform patients about uncertain evidence base**

IQWiG identified a few studies on allogeneic transplantation that could not however be included in the assessment, as the results did not distinguish between related and unrelated donors. In these studies, a reduced-intensity conditioning regimen was applied, which is nowadays standard treatment in patients with Hodgkin's lymphoma who undergo allogeneic SCT. This treatment variant is less aggressive (toxic) and therefore better tolerated. These studies indicate that patients who received allogeneic SCT with a reduced-intensity conditioning regimen survived longer than patients who had been treated with chemo- and/or radiotherapy alone.

All patients in these studies had already undergone one or more unsuccessful therapy attempts (including autologous transplantation). Despite the gaps in knowledge, in IQWiG's opinion it is therefore justified to offer allogeneic transplantation with a reduced-intensity conditioning regimen to these patients, including transplantation with an unrelated donor, as other therapy alternatives are not available to them. In order to close knowledge gaps, IQWiG recommends a separate analysis of data on transplants from related and unrelated donors in all future studies and publications. This also and specifically refers to studies that include a comparison with treatment without allogeneic SCT.

In IQWiG's opinion, it is indispensable that patients are informed in full detail about the currently still uncertain evidence base before any decision for or against allogeneic transplantation is made.

Provided by Institute for Quality and Efficiency in Health Care

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