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Autologous stem cell transplantation: Understanding the treatment

Information for transplant-eligible patients with multiple myeloma

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With patients, for patients

Our work focuses on the health and quality of life of patients and their families. Doing our best every day to achieve this is a central part of our corporate philosophy. That is why our commitment goes far beyond researching innovative medications. We develop information, training and assistance programs and services, because we want patients and their families to be able to experience special and everyday moments in the same way they took for granted before the diagnosis.

This brochure has been developed in collaboration with practicing physicians and affected patients.

For better patient care.

THE POWER OF **PURPOSE®**

Shaping lives – that's what oncological research is all about.

Dear patient,

In this brochure, we want to tell you and those close to you about all the important aspects of autologous stem cell transplantation and answer your questions about the treatment. Among other things, you will learn what autologous stem cell transplantation is and into which treatment phases the therapy can be divided. We have also given you room in the brochure to record your questions and comments, and to take notes.

We also hope this brochure will be a source of encouragement for you! Scientific research has achieved a great deal, especially in recent years, and there are other promising concepts in the pipeline.

All good reasons, in other words, to start the treatment confidently and decisively. We wish you every success with it!

Your Janssen Oncology Team

Janssen Oncology

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Foreword

Transplantation of a patient's own – autologous – blood-forming stem cells, also known as auto TX for short, has been a tried and trusted method of treatment in the field of hematology for four decades. In principle, it is a highly effective chemotherapy treatment to eliminate tumor cells in the bone marrow, in lymph nodes or anywhere else in the body. In order to protect the healthy bone marrow, especially the production of healthy blood, from the aggressive chemotherapy, the blood-forming stem cells are taken from the patient and stored in frozen form in liquid nitrogen. In the 1970s and 1980s, the cells were surgically removed by means of aspiration from the pelvis to obtain the liquid bone marrow in which the stem cells live. In the 1980s, German scientists from Ulm and Heidelberg discovered that, under certain conditions – generally when the bone marrow is stressed – stem cells are released into the blood in high numbers, from where they can be removed. This is done by means of continuous-flow centrifugation of blood over a four-hour period. This is called stem cell apheresis.

It remains undisputed that autologous stem cell transplantation after high-dose therapy with a cytostatic active substance is still the most effective form of therapy in the treatment of multiple myeloma. Over the past 30 years, it has become a cornerstone of primary myeloma treatment and has shed its risky image. In Germany, there are practically no patient deaths when this method is used. The side effects of this chemotherapy are mitigated, for the most part, by giving patients supplementary medication. Nevertheless, it is a strenuous treatment that weakens the body, and causes nausea and inflammation of the mucosa. Some patients are only able to continue with their regular everyday activities and resume their careers after three months, while others can do so after just three weeks. The body's own immune system regenerates quickly and long-term prophylactic precautions are not required.

Read the brochure and allow your fear of the great unknown, autologous transplantation, to be dispelled by gaining a better understanding of it.

Yours sincerely,
Prof. Dr. med. Igor-Wolfgang Blau
Charité University Hospital Berlin

Contents

	Introduction	7
	Explanation of the symbols	8
01	The treatment phases of ASCT	9
02	The treatment phases in detail	10
03	The treatment phases timescale	11
04	What are the advantages of ASCT?	16
	What are the risks?	17
05	You are not alone	18
	My cancer companion	19
	The well-informed patient ...	20
	Self-help organizations	21
	References	23

Introduction

Your physician has given you this brochure because your physician thinks that autologous stem cell transplantation (ASCT) is a suitable option for you. In this brochure, you will find important information about the autologous stem cell transplantation process.

What is ASCT?

ASCT is used in the treatment of patients with blood cancer, particularly in the treatment of multiple myeloma. ASCT incorporates so-called high-dose chemotherapy, during which myeloma cells are destroyed. However, this also damages healthy cells in the bone marrow. Therefore, your own blood stem cells, collected beforehand, are transplanted back into your body to stimulate blood formation again after the treatment.

The blood stem cells used originate from you. This type of stem cell transplantation is called "autologous" transplantation, after the Greek word for "self." Alternatively, in an "allogeneic" transplant, the blood stem cells come from a donor. However, this form of transplant is rarely used to treat multiple myeloma.

Why ASCT?

ASCT is particularly suitable for younger, "fit" myeloma patients. In 20–60 % of cases, the treatment can achieve complete remission – disease regression – which can last for several years.[1] There are, therefore, advantages to ASCT, however, it can also be risky.

Explanation of the symbols

On the following pages, you will encounter some symbols, which we will explain briefly here. You can refer to this page any time to see what the symbols stand for.

Long stay
This treatment may be associated with a long hospital stay

Syringe
During this treatment, you will be given an injection

Infusion
This treatment is administered intravenously via an infusion

Anesthesia
During this treatment, you may be given a local or general anesthetic

Side effects
Side effects can occur during treatment

Radiation therapy
This treatment includes radiation therapy

At home
This treatment can take place at home

Hospital
This treatment can be administered in a hospital

Physician
This treatment can be administered by your physician

A low-bacteria diet is important

Bathe or shower every day

Put on fresh clothes every day

Change towels and bedding daily

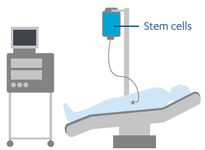
Use a soft toothbrush and mouthwash

Exercise regularly but don't over-exert yourself

Phase 2: ASCT

High-dose chemotherapy
You will be admitted to hospital as an inpatient two to four weeks after the stem cell apheresis. You will be given chemotherapy, which is usually administered intravenously via a venous catheter (into a vein in the arm). The purpose of this is to destroy the remaining myeloma cells.

Transplantation
Your stem cells will then be transferred back into your body via a venous access on your arm. These will then migrate to the bone marrow where they will form new, healthy blood cells. This will reinitiate the blood formation process in your body. This will take two weeks. You will then recover in the weeks following your discharge.



Phase 3: After the ASCT

Follow-up treatment
Anti-myeloma therapy may be necessary to destroy any residual myeloma cells in your body, which will significantly improve the success of your treatment. This so-called **“consolidation”** usually takes place with your treating physician over the course of several weeks. Maintenance therapy may take place at a later stage. In addition, you will undergo regular check-ups in the form of tests and examinations. These will include tests to determine your response to the treatment.

Recovery time
Your body will be weakened by the treatments and it will take some time for new blood and immune cells to form from the transplanted stem cells. This will make you particularly susceptible to infections. You should, therefore, take adequate hygiene measures and avoid contact with individuals you are acquainted with who are unwell. Discuss with your physician whether a course of rehabilitation would be beneficial for you. You can make an application to social services for this while you are still in the hospital.

04 What are the advantages of ASCT?

ASCT is currently the therapy of choice in suitable patients, since it can significantly improve patients’ chances of survival.[1,3]

“An autologous blood stem cell transplantation after first-line myeloma therapy, which is now routine practice, currently offers patients the optimum healing process, which I am happy to say, in my case, has resulted in my reengaging in activities with my family, as well as in my free time and at work.”

Andreas D. (61), male, stem cell transplant in 2013

01 The ASCT treatment phases

The treatment consists of three phases, which are subdivided into several steps. The ASCT itself is actually only a small part of the process and constitutes the second phase of the treatment. A detailed overview of the individual steps can be found on the following pages.

Phase 1: Before the ASCT (stem cell mobilization)

- **Screening examination**
- **Preparing for ASCT (10 days)**
  - Administration of so-called mobilization therapy over two days to acquire as many stem cells as possible from the bone marrow
  - After a pause, a growth factor is administered over five days
  - This is used to stimulate stem cell reproduction in order to collect as many stem cells as possible
- **Collection of stem cells** from the blood or, in rare cases, from the bone marrow (stem cell apheresis)

Phase 2: ASCT

- **High-dose chemotherapy** to destroy the remaining myeloma cells
- **Transplantation** of the stem cells previously acquired from the patient
- **Regeneration time** until the transplant takes (two weeks)

Phase 3: After the ASCT

- **Follow-up**
  - If required, maintenance or consolidation therapy to maintain a response for as long as possible
  - Follow-up tests and procedures
- **Recovery time** can be between 3 and 12 months

NOTE:
You may experience side effects during your treatment. In this case, please contact your treating physician immediately. If necessary, you can also avail of psychological support. Depending on the progression of the disease, a longer hospital stay should be anticipated, which can vary from patient to patient.

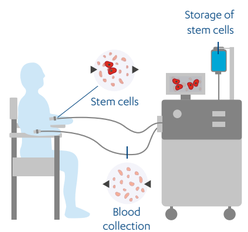
02 The treatment phases in detail

Phase 1: Before the ASCT (stem cell mobilization)

Screening examination
In order to ensure that your ASCT runs smoothly, several tests must be performed before, during and after your treatment. You may already be familiar with many of these tests. The most important test that must be performed is a bone marrow aspiration and biopsy. This involves taking a bone marrow sample from your pelvic bone. The results of this biopsy can be used after the transplant to determine whether the treatment has been successful.

Preparing for the ASCT
Induction therapy is usually administered as preparation for ASCT. This is designed to ensure that the number of myeloma cells in the bone marrow is reduced and kept as low as possible before the stem cells are removed. This can take up to 24 weeks.[2]
Ten days before the stem cells are collected, you will be given chemotherapy, as a result of which the stem cells from the bone marrow are released in greater numbers into the bloodstream. For this reason, this step is also called **“stem cell mobilization”**. Consequently, in most cases, it is possible to remove the stem cells from the blood instead of from the bone marrow.

Collection of stem cells (stem cell apheresis)
Your blood will be taken intravenously from one of your arm veins. The stem cells contained in the blood will then be isolated using a device, portioned into three transplant batches as a rule, and then frozen. Your blood will then be reintroduced into a vein in your other arm.



03 The treatment phases timescale

This illustration shows you how ASCT treatment usually works. However, this may differ from patient to patient.

Phase 1

Induction therapy

The treatment is designed to keep the number of myeloma cells in the bone marrow as low as possible.

Up to 24 weeks

Preparation for ASCT (mobilization)

Chemotherapy during the mobilization phase promotes the release of stem cells from the bone marrow into the bloodstream. The production of the stem cells is stimulated by growth factors.

10 days

Stem cell collection

The stem cells are usually taken from the blood. In rare cases, bone marrow aspiration under anesthetic (hospital stay) may also be necessary.

1–2 days

Phase 2

High-dose chemotherapy followed by stem cell transplantation

The treatment usually consists of high-dose chemotherapy, which is administered either as a single dose or over two days and kills all the cells in the bone marrow. Approximately one day later, the stem cells are returned to the patient's body (transplanted) by means of a short infusion. The stem cells are frozen and stored until then. After the transplant, they find their way into the bone marrow where they form new blood cells. This process takes a few days to complete. During this time, the body is very prone to bleeding and susceptible to infection. You will have to stay in the hospital for about three weeks until sufficient numbers of new cells have been produced.

3–6 weeks

Phase 3

Follow-up

In order to determine the response to the treatment, a bone marrow aspiration procedure as well as blood tests are usually performed over several weeks.

Up to six weeks

Consolidation/ maintenance therapy

Following ASCT, further antimyeloma therapy can be given to destroy any remaining myeloma cells. The duration of treatment depends on the therapy.

A few weeks

Recovery time

The treatment weakens your body. It is, therefore, important to look after your health following the treatment. The regeneration time varies from patient to patient.

Approx. one year

Screening examination

A few days

WEEK 0 24 26 32 44 50 90

NOTE:

You will need someone to look after you (a family member or a good friend) to help you with your recovery. This person should accompany you so that you are in a better position to recognize any unexpected complications should they arise.

Over time, you will gradually feel stronger and more confident in undertaking everyday activities.

This curve shows the various phases of your symptoms during the different treatment stages. However, this varies from patient to patient.

What are the risks?

The main risks of ASCT are the possible side effects of the myeloma treatment and the high-dose chemotherapy. Your immune system will also need a longer period of regeneration after such intensive treatment, which is why you should take special precautions for your own protection in the short term. If you experience complications during your ASCT, you will need to prepare yourself for a longer hospital stay, although this is rarely the case.

Since not all patients respond to ASCT to the same extent, it is difficult to predict in advance exactly how successful the treatment will be. Therefore, before making a decision, it is essential to carefully weigh up the benefits and risks of ASCT during the consultation with your physician.

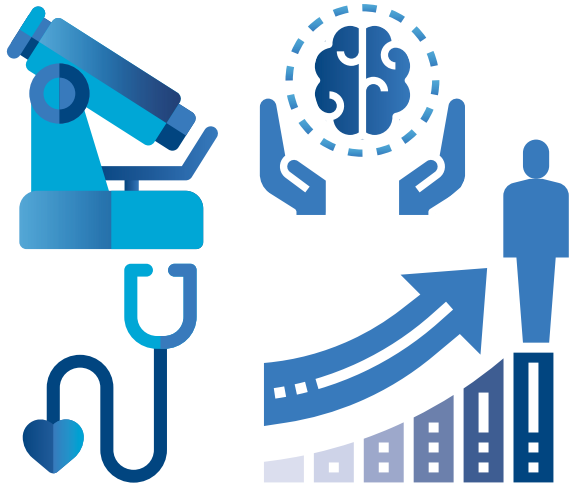
05 You are not alone

stem cell transplants 2018

You are not alone. Almost 43,000 people in Europe received a stem cell transplant in 2018.[4]

Stem cell transplantation has been further refined over the last 30 years.[5] The chances of recovery have improved in tandem with technological advances, the therapeutic procedure itself and the medical care provided.

ASCT HAS BEEN AVAILABLE FOR THE LAST 30 YEARS



MEIN KREBSRATGEBER

Your personal companion for all stages of cancer

MEIN KREBSRATGEBER
is an internet portal provided by Janssen for cancer patients, their families and other interested parties.
The information portal is designed to be a personal companion, providing information and assistance at all stages of the disease.

A summary of the most important information:

- Reliable information on the latest scientific developments
- Valuable everyday tips for living with cancer
- Over 80 videos with facts and practical aids
- Directory of physicians including more than 500 oncology practices
- Contact person at self-help organizations
- A way of sharing information with others in the same situation

You can find more information from Janssen on multiple myeloma at:
www.krebsratgeber.de/MM

The well-informed patient ...

A diagnosis of multiple myeloma is an unexpected blow to those affected and their families: Suddenly, they are confronted with medical routines and concerns about social welfare entitlements. Not only is the barrage of new information often overwhelming – the tests and procedures they need to deal with, the initial diagnosis and the associated treatment can also have a significant impact on patients.

Taking part in a self-help initiative can help them to manage the personal and social stresses that accompany the illness. Various research findings and reports on patient experiences indicate that those who participate in self-help initiatives are less prone to depression and physical symptoms induced by psychological issues. They are also more independent and self-confident than other patients in comparable situations. There are many reasons for this: In a self-help group, you learn to accept your illness and live with it. You benefit from a new quality of life and are better informed about your symptoms and the treatment options. Sharing information with those who are similarly affected is particularly helpful – especially when major treatment decisions are pending, such as a stem cell transplant. Talking to others can help you to rebuild your confidence and strength before the treatment.

For me personally, the decision, made at an early stage, to join a self-help initiative was the best way to confidently share my thoughts and feelings with other patients – and ultimately led to me becoming a well-informed patient.

Yours sincerely,
Andreas Dirksen
Group Spokesperson for Hannover (Myelom Deutschland e.V.)

Patient association groups

Self-help groups and patient association groups

Arbeitsgemeinschaft Multiples Myelom with forum for patients and relatives
www.myelom.org

Myelom.Online e.V.
Phone: +49 (0) 4535 59 11 26
www.myelom.online

Leukämiehilfe Rhein-Main e.V. (Leukemia Support Rhine-Main)
Phone: 06142 3 22 40
www.leukaemiehilfe-rhein-main.de

Myelom-Gruppe Rhein-Main g.e.V. (Myeloma Group Rhine-Main)
Phone: 06142 3 22 40
www.myelom.net

Digital self-help groups

yeswecan!cer and YES!APP Digital self-help group
www.yeswecan-cer.org
www.yeswecan-cer.org/die-yes-app

Your notes

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More about our **patient management:**

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Janssen With Me®

Your website containing information on diseases on which we are conducting research.
www.janssenwithme.de

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