

Herzlich
Willkommen

Macular degeneration

Information for patients

Macular Degeneration treatment with autologous adult stem cells from your own bone marrow.

What is Macular Degeneration?

Macular degeneration is a retinal degenerative disease that causes progressive loss of central vision. The risk of developing macular degeneration increases with age. The disease most often affects people in their sixties and seventies. Macular degeneration is the most common cause of vision loss in individuals over the age of fifty-five.

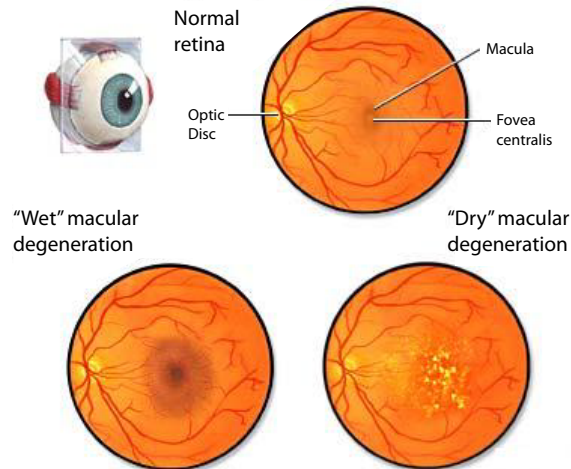
Clinical description

Central vision loss from macular degeneration is caused by the degeneration of the macula. The macula is the central portion of the retina responsible for perceiving fine visual detail. Light sensing cells in the macula, known as photoreceptors, convert light into electrical impulses and transfer these impulses to the brain via the optic nerve. Central vision loss from macular degeneration occurs when these photoreceptors cells in the macula degenerate.

Individuals with Macular degeneration may first notice a blurring of central vision, particularly encountered, when performing visually detailed tasks such as reading and sewing. Blurred central vision may also make straight lines appear slightly distorted or warped. As the disease progresses, blind spots form within central vision. In most cases, if one eye has macular degeneration, the other eye will also develop the disease. The extent of central vision loss varies according to the type of macular degeneration.

Dry macular degeneration

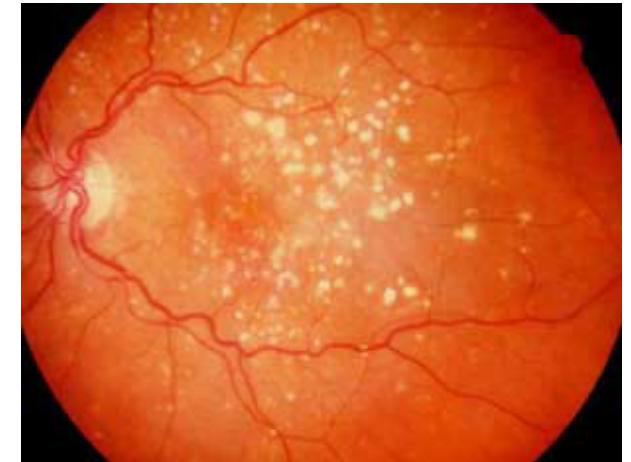
There are two types of macular degeneration: dry and wet.



Dry macular degeneration accounts for about 90 percent of all cases. Dry Macular degeneration is sometimes called atrophic, nonexudative, or drusenoid macular degeneration. With dry macular degeneration, yellow-white deposits called drusen accumulate in the retinal pigment epithelium (RPE) tissue beneath the macula. Drusen deposits are composed of waste products from photoreceptors cells. For unknown reasons, RPE tissue can lose its ability to process waste.

As a result, drusen deposits accumulate in the RPE.

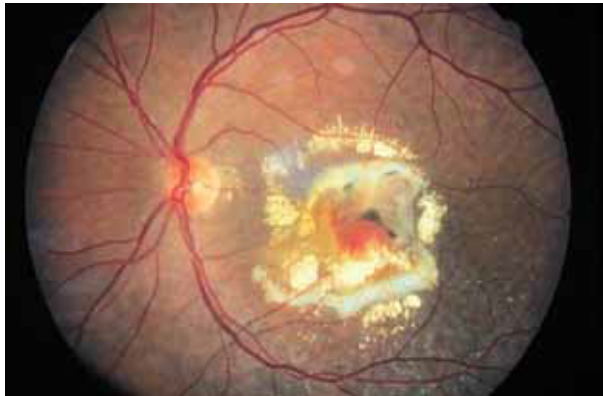
Drusen deposits are typically present in patients with dry Macular degeneration. These deposits are thought to interfere with the function of photoreceptors in the macula, causing progressive degeneration of these cells. Drusen deposits can, however, be present in the retina without vision loss. Vision loss from dry macular degeneration occurs very gradually over the course of many years. Central vision may even remain stable between annual eye examinations.



Individuals with dry macular degeneration do not usually experience a total loss of central vision. However, their vision loss may make it difficult to perform tasks that require finely focused vision. Although there is extensive research efforts to find treatments for dry macular degeneration, at this time no proven treatments exist.

Wet Macular Degeneration

Wet macular degeneration accounts for about 10 percent of cases. Wet macular degeneration is also called choroidal neovascularization, subretinal neovascularization, exudative, or disciform degeneration. In wet macular degeneration, abnormal blood vessel growth forms beneath the macula. These vessels leak blood and fluid into the macula damaging photoreceptors cells.



Wet macular degeneration tends to progress rapidly and can cause severe damage to central vision. It is critical that wet macular degeneration be diagnosed before extensive vision loss occurs. Therefore, individuals should consult with an ophthalmologist at the first sign of blurred or distorted central vision.

Diagnosis

Along with regular examinations by an ophthalmologist, individuals can test their eyesight for possible symptoms of macular degeneration roughly with a simple home test, known as the Amsler grid. The Amsler grid consists of parallel and perpendicular lines, looking much like a sheet of graph paper. By focusing on a marked spot in the middle of the grid, one can assess whether the lines appear blurred or distorted.

While the Amsler grid is not a substitute for expert medical diagnosis, it does allow individuals to check their eyesight regularly for possible symptoms of macular degeneration. To receive a free Amsler grid, please contact The Foundation Fighting Blindness (<http://www.blindness.org/>).

Risk Factors

The causes of both, dry and wet macular degeneration are not well understood. Studies are examining whether genetic inheritance, diet, cigarette smoking, light exposure, cardiovascular disease and hypertension are significant risk factors for macular degeneration.

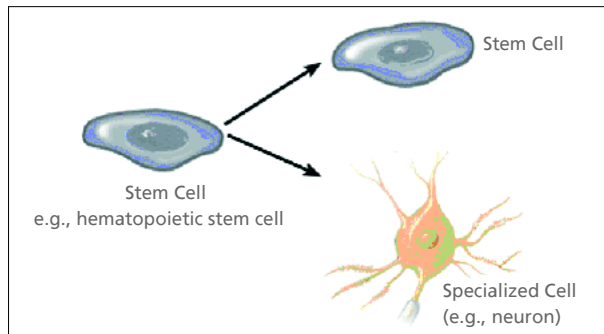
Inheritance

When a disease like AMD occurs late in life, scientists often have difficulties finding surviving family members to study whether the disease is genetically inherited.

Initial studies have found an increased incidence of AMD (Age dependent Macular Degeneration) within families. Such evidence indicates that inheritance plays some role in the disease. However, the magnitude of genetic inheritance is not fully understood at present. Scientists are currently conducting large scale studies to determine whether AMD is passed by a direct inheritance pattern such as autosomal or recessive.

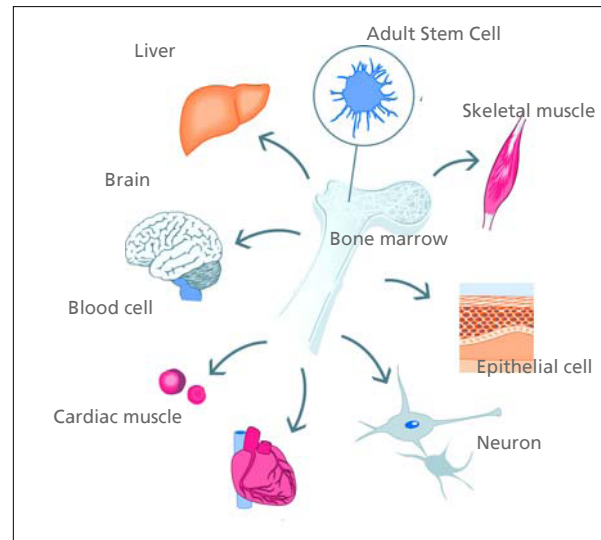
About Stem Cells

The discovery of the stem cell has led to a revolution in modern medicine. Stem cells are in fact, the “smart cells” of our bodies. These cells migrate to injured areas within the body and transform themselves into new tissue cells that replace the damaged ones. The body repairs itself by continuously producing new cells and tissues in this manner.



Stem cells have the capacity to multiply and to renew themselves almost indefinitely. This contrasts with nerve cells, muscle cells and blood cells, which cannot multiply themselves and have limited life spans. Stem cells can also develop into specialized cells.

Stem cells from the bone marrow can develop into evolved photoreceptors as in mature pigment epithelium cells or produce proper stimulants as neurohormonal media, specific enzymes and mitochondrial.



About stem cell therapy: Stem cell activity in Macular Degeneration

Retrobulbar injection of stem cells should first

prevent the worsening of dry and wet macular degeneration by reducing the Drusen deposits in the retinal pigment epithelium beneath the macula. It should also prevent the destruction of the photoreceptors in the dry type and in the wet type, reactivate proper microvessel activity thus reducing the abnormal blood vessel growth beneath the macula that is producing such rapid destruction of the photoreceptors cells.

The XCell-Center Macular Degeneration treatment

The entire procedure consists of the following phases:

eligibility, stem cell collection and processing, stem cell treatment, and follow up.

Objectives

The goal of this treatment is possibly to repair damaged tissue or to reactivate existing photoreceptors and epithelial pigment cells with the ultimate goal of arresting the degeneration and improving visual function.

Type of treatment

On the first day, Stem cells are collected, sterilized, selected and concentrated in a sample that will be used the next day for implantation. The stem cells are collected from your own pelvic bone (iliac crest) marrow before being sent to the lab. The implantation method currently employed is called retrobulbar insertion.

Eligibility phase

If you meet the following conditions, you are eligible for treatment:

- Wet or dry macular degeneration diagnosed from your ophthalmologist possibly supported by OCT, Fluorangiographies and Retinographies
- The XCell-Center medical staff reviews and approves your specific case
- Your bone marrow contains a sufficient quantity of viable stem cells. This is assessed by the lab during processing.

These pictures show the Bone Marrow Collection Procedure



Arrival at XCell-Center



Preparation



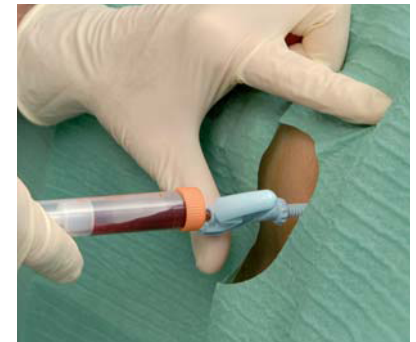
Application of local anesthetic



Disinfection of the collection site



Needle insertion into the hip bone (iliac crest)



Sample collection

Stem Cell Collection and Processing

Prior to scheduling bone marrow collection, you will be asked to fill out the patient consent form. This form grants explicit written permission for bone marrow collection.

You must discontinue using any blood diluting medications at least 10 days before your collection date. You should consult your physician before discontinuing the use of blood diluting drugs.

When we greet you on the collection day, we'll have everything prepared to begin collection and make it comfortable for you.

Our physician will collect approximately 150 – 200 ml of bone marrow from your hip bone.

Stem cell collection is performed as an out-patient procedure under local anesthesia in sterile conditions. It is comparable in pain to a dentist visit. During the collection, you will barely feel the needle insertion into your hip bone. Afterwards, the collection site might look like a "blue spot" and be a bit painful for 3 – 4 days. Normally, there are no other side-effects. Theoretically, there is a small risk of infection. We minimize this risk by working in a sterile environment.



Within 24 hours, the stem cell samples are processed and quality tested by a highly specialized laboratory in totally sterile, clean room conditions. Since they are kept in sterile tubes and never come into contact with the air, these samples cannot be contaminated.

Bone marrow processing and quality testing consists of:

- Stem cell isolation – stem cells are separated from the red blood cells and blood plasma.
- Stem cell counting
- Stem cell vitality measurement

Stem Cell Implantation

Your high-quality stem cell sample will be implanted by retrobulbar injection into the eye space under local or general anesthesia.

Possible Adverse Events from the treatment

- Sometimes, patients might experience intensive red eye caused by the subconjunctival introduction blood cells contained in the stem cell fluid. This increases the eye stimulation and is known in medicine as "self-blood-therapy" (auto-emoterapia). The eye will become normal in 3 - 5 weeks maximum. In very rare cases these blood cells can migrate down underneath the eyelid and the skin can appear bruised. In this case, as for subconjunctival red eye, there is no reason to be concerned because the procedure was performed in absolutely sterile conditions. This blood actually stimulates the organ and the body will absorb it in a few days.

Treatment Advantages

- Simple
- Out patient
- Low overall risk

Follow-up

Once you have returned home, a member of our medical team will regularly monitor your progress via telephone and email. For your convenience, a telephone "hotline" is always at your disposal.

Cost

The total price for the treatment is 10.545 Euros.

This price includes:

- Bone marrow collection and transportation
- Stem cell administration
- XCell-Center medical fees
- XCell-Center administrative fees

This price **does not include travel expenses** such as

airfares and meals, or accommodation costs.

If you have tested positive for hepatitis or HIV, we will invoice you an additional € 1,000 relating to special precautionary and disinfection measures.

General

No additional charges will be incurred unless you are required to extend your stay at the medical center as a result of complications. Costs do not include additional stem cell treatments. If another treatment is necessary, we will discuss potential options with you.

You will receive an invoice one week prior to treatment. This invoice must be paid in-full before treatment can begin.

Note: If your bone marrow sample is negative or the stem cells cannot be administered due to unforeseen medical circumstances, you will only be required to pay charges incurred to that point. In the case of a negative bone marrow sample, it might be possible to schedule another bone marrow collection.

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