

CLWP and LEWP: Non-interventional prospective study on the efficacy and feasibility of punctal occlusion after allo transplants, patient information and informed consent



## Non Interventional Prospective Study on the short- and long-term efficacy and feasibility of routinely installed punctal plugs for severe dry eyes after allogeneic stem cell transplantation

### 1.1.1 INFORMATION FOR THE PATIENT

#### ***Introduction***

This non-interventional prospective study is conducted by the European Blood and Marrow Stem Cell Transplantation Group (EBMT).

The study will collect details about the treatment with punctal plugs you receive for dry eyes. Your participation in this non-interventional prospective study does not influence the choice of the treatment you will receive; you will get exactly the same treatment as you would have otherwise received. The only difference is that your doctor provides some additional data to the EBMT.

The information obtained from your treatment and many others will be used to study the efficacy of the use of punctal plugs for the treatment of dry eyes after allogeneic stem cell transplantation and to achieve and spread better knowledge about this treatment.

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After allogeneic stem cell transplantation a patient may develop severe dry eyes, most of the times associated with chronic graft-versus-host-disease. Standard therapies for dry eyes are topical lubricants that will relief symptoms in some patients. In many however normal daily activities are impaired by the dry eye symptoms. Application of autologous serum eye drops or topical cyclosporine may relief symptoms in some patients.

For patients insufficiently responding to these treatments installation of punctal plugs may be helpful. These plugs occlude these canaliculi and thereby reduce the outlet of the few tear drops and increase the moistness of the eye.

### ***Personal Data Privacy Protection***

Your data collected during the treatment of your disease will be filed non-identifiably. Only authorized and qualified collaborators of the government bodies and of the hospital have been allowed access to the data of this study.

A unique code number will protect all medical data, collected during the study; we never use the patient or donor full name. No personal data will be used in any study documentation, in reports or publications.

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**1.1.2 PATIENT CONSENT**

<p><b>Patient's Initials and Date of Birth (or patient's label)</b></p> <p>Initials: .....(first name(s)-surname(s))</p> <p>Date of birth:        .....                           <i>dd</i>        <i>mm</i>        <i>yyyy</i></p>
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<p><b>Study number</b></p> <p>(provided by data office)</p>
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I ..... (Patient, Parent, Guardian) have been informed to my satisfaction regarding data collection and I consent to non-identifiable data of my treatment for the non-interventional prospective study on punctal occlusion for the treatment of severe dry eyes after allogeneic stem cell transplant being reported to the EBMT.

Signed .....

Date .....

(Witness .....)

I confirm that I have explained the procedure of the insertion of punctal plugs for the treatment of dry eyes; and the process regarding the collection and storage of data to this patient who appears to have fully understood them.

Signed .....

Date .....