Punctal Occlusion
EBMT/CLWP Non-Interventional Prospective Study

BACKGROUND INFORMATION

Study Objective:

To study in time the short- and long-term efficacy and feasibility of routinely installed punctal plugs for severe dry eyes after allogeneic stem cell transplantation

Inclusion criteria:

1. Diagnosis of dry eyes (with onset of > 3 months?) after alloSCT

    One or more of the following distinctive symptoms are needed:

    distinctive: new onset of dry, gritty or painful eyes, cicatricial conjunctivitis, keratoconjunctivitis sicca or confluent areas of punctuate keratopathy
    other features: photophobia, periorbital hyperpigmentation, blepharitis (erythema of the eyelids with erythema)
    AND (obligatory) low Schirmer's test without anesthesia
    mean of both eyes ≤ 5 mm at 5 minutes, or
    mean values of 6-10 mm at 5 minutes in patients with sicca symptoms or new keratitis detected by slit lamp examination

2. eye symptom score ≥ 2 for at least two months since last adjustment in topical lubricants prescription
3. installation of punctal plugs is a routine procedure performed by an experienced ophthalmologist
4. routine usage of Schirmer's test, tear film breaking time and fluorescein punctate staining of the cornea
5. Patient age at transplant ≥ 18 year.

Exclusion criteria:

1. active ocular infection or other past or present eye disease
2. prior punctal plug insertion
3. dry eyes before SCT
4. Sjögren's disease prior to SCT
5. use of contact lenses

Condition of the eyes, explanation of parameters

Subjective parameters

    a. 0-10 patient reported intensity scale of worst eye symptom (visual analogue scale symptoms score (VAS), according to NIH Consensus)[4]

    b. type and average number of daily topical lubricant(s) medication (diminished use should not have resulted in worsening of symptoms)
- i. not on a daily basis
- ii. thrice daily or less
- iii. 4-6 times/day
- iv. >6 times/day

Objective teardynamic parameters

    c. mean Schirmer's test of both eyes (according to NIH Consensus)[4]

    d. tear film break-up time (TBUT; <5 sec. is abnormal)

Objective corneal damage parameter

    e. standard fluorescein punctate staining (measuring ocular surface disease)****[5]

complications of punctal plug insertion; of notice:

- loss will not be judged as complication or failure in case of prompt replacement;
- need for placement in upper nasolacrimal canaliculi is also not judged as complication or failure)

Registration FORM (version 14-10-2009)   *Please send form to:*CLWP Data Office   *or fax*   +49-180-500-290-623 *or*
LUMC Postzone S-5-P   +49-711-4900-872
P.O. Box 9600
NL-2300 RC Leiden
The Netherlands