T.C. SULEYMAN DEMIREL UNIVERSITY DERMATOLOGICAL CONSTENT FORMS BOTULINUM TOXIN KOD KRY.02.PR.02 YAY.TAR. 05.02.2024 REV.NO:01 SAYFA SAYISI: 5

BOTULINUM TOXIN PROCEDURE INFORMED CONSENT FORM

The objective of this form is to enable your participation into the decision making process about your healthcare by informing you.

This form has been designed in order to meet the needs of many patients under most conditions, nevertheless, it should not be considered as a document containing the risk of the entire applicable treatment. Based upon your individual healthcare, your physician may provide you with different or additional information.

After acquiring the advantages and possible risks of diagnosis, medical treatment and surgical interventions, it is up to your decision whether or not to accept these procedures. You are entitled to refuse to be informed except for the legal and medical necessities or withdraw your consent at any time.

What You Need to Know About Your Disease

The substance used in botulinum toxin procedure is a protein secreted by bacteria called Clostridium botulinum. This agent blocks the electrical transmission from the nerves to the muscles, and temporarily reduces or terminates the function of the muscle at the area. When muscular function is lost and not able to contract, the wrinkles on the skin either diminish or go away. During the effect of botulinum, you will be unable to use facial expression muscles even if you want to. Therefore, you will lose several of the joy and sadness expressions on the face, particularly the expressions of surprise and anger. Within that period, the skin finds the opportunity to get better. Botulinum toxin is not a miracle. It will make no permanent change on your face. Besides, it will not take your appearance back to what it used to be 20 years ago. Botulinum toxin operations provide temporary recovery in the wrinkles on certain parts of your face only.

Fields of Implementation:

- Horizontal lines on the forehead
- Lines between two eyebrows leading to knit appearance
- Lifting upwards of the sides of both eyebrows
- Lines and wrinkles on the sides of both eyes showing aging of the face (crow's feet lines)
- Correction of the lines on the lower eyelid and slit eye complaint
- Lifting of the tip of the nose
- Upper gum getting visible when laughing
- Vertical lines on the upper and lower lip (smoking lines or barcode lip lines)
- Lifting upward of the lip corners
- The horizontal line between the lower lip and the chin
- Grinding or clenching of the teeth
- Making the chin skin smoother, limproving the orange peel appearance
- Therapy of the horizontal lines and vertical tapes on the neck
- Botulinum toxin can be used for treatment of excessive sweating in hands, feet, face and armpits.

What Kind of Treatment/Intervention Will be applied?

The therapy area being cleaned 30-45 minutes before, the local anesthetic cream is applied. The Botulinum toxin is injected intramuscularly from a few points with very thin tipped syringes. During the practice, no complaint of pain occurs that disturbs the patient. The patient is not put to bed but taken to half sitting position. Injections are applied with 30 G syringes intramuscularly with an angle of 30-45 degrees. An average of 4-7 international units of botulinum toxin is injected to each point (The dosage can be changed by your physician). The entire procedure takes about 10-15 minutes.

Beware the Following after Therapy

- Facial muscles that are injected with botulinum toxin should be exercised in the first 2 hours. The eyebrows should be raised up, the eyes should be made as if you were angry or they should be squinted. This process will increase the effectiveness of botulinum toxin on the muscles.
- Cold compress should be applied to the face with an ice pack wrapped in a towel for 15 minutes
 every 2 hours, starting immediately after the treatment in order to reduce oedema, redness and
 bruising that may occur on the face. Cold compress should be continued for the first 24 hours.
 Despite all these precautions, bruising may occur on the face, but it will disappear spontaneously
 within 1 week.
- If the physician deems appropriate, various creams and oral medications can be used for the treatment of oedema, redness and bruising on the face. No creams and oral medications should be used without consulting the physician.
- You should not lie face down for the first 4 hours. On the first night, it will be more convenient to sleep on your back with a high pillow.
- In the first 24 hours, the face should not be rubbed, make-up or massage should not be applied to the face, hair should not be dyed and eyebrows should not be plucked.
- In the first 24 hours, hot baths and showers should not be taken, baths or tanning booths should not be visited and intense sun should be avoided, since these may cause redness and oedema on the face.
- Heavy and intense sports, body-building, plates and yoga, which may cause redness and oedema on the face by increasing blood pressure, should be avoided in the first 24 hours.
- Due to the risk of infection, you should not swim in the pool for the first 3 days.
- For the first 3 days, alcohol, cigarettes, aspirin, pain relievers (ibuprofen, naproxen), blood thinners (coumadin, warfarin, dopidogrel), green tea should not be used, foods containing garlic, fish oil, vitamin C, vitamin E, niacin, ginkgo, ginseng, echinacea and high levels of sugar, sodium and caffeine should not be consumed.
- Skin care and peeling should not be applied to the face for the first week.
- Since the methods such as mesotherapy, PRP, HIFU (High Intensity Focused Ultrasound), laser and radio frequency to the area that is injected with botulinum toxin will shorten the effect time of botulinum toxin, these methods should not be applied without the approval of the physician.
- The use of vitamins and supplements can shorten the effect time of botox.

How Long Does the Botulinum Toxin Effect Last?

Botulinum toxin effect starts 3-7 days after the procedure and lasts 3-4 months. The effect of the botulinum toxin can last about 12 months as the number of the procedures increase.

Is There any Harm in Botulinum Toxin?

Botulinum toxin has been used for aesthetic purposes for 15 years. Its use in muscular diseases dates back much older. No side effect of botulinum toxin was found out within such period. Botulinum toxin approved by the Federal Drug Administration is used commonly throughout the world.

Risks of Botulinum Toxin Procedures

- Rash, bruise, abscess at the injection spot may occur rarely and last 1-2 days.
- There might be a temporary headache.
- There may be pain, risk of infection, temporary loss of sensation or function in the treated area.
- Losses of function, which may develop depending on the treated areas, but will improve over time, can be listed as follows:
 - o Ptosis (droopy eyelid) in the treatments between the eyebrows, and forehead,
 - o Inability to make whistling gesture in lower and upper lip treatments,
 - o Difficulty in swallowing in neck area treatments.
- Pitosis (droopy eyelid) gets better in time, If necessary, treatment may be done with botox injection.
- Chewing difficulties may occur for 1-2 weeks after masseter botox.

Diagnosis	 	
Treatment/procedure to be applied_	 	

Should you not intend to be informed about the purpose, duration, advantages, success ratio, potential risks and complications and alternative options of the treatment to be applied and as well as about the subsequent potential risks in case you do not accept the treatment, please declare so below with your hand writing.

I hereby declare that;

My attending physician informed me about my disease, the treatment option to be applied, its duration, advantages, success ratio, the fact that it does not necessarily guarantee the recovery of current status, period of healing, potential risks and complications, alternative techniques, the potential situations I will experience on the condition that I reject the treatment and compulsory performance of an additional operation/intervention/procedure if deemed necessary and s/he answered all my questions regarding these matters.

Above mentioned procedure has been disclosed to be performed on myself/patient I legally represent by the physicians, nurses as well as other healthcare professionals under the authority, surveillance and control of my attending physician.

I have been informed that if required, anesthesia will be performed by an anesthetist, sedation will be performed by an anesthetist or another physician competent in sedation and local anesthesia will be performed by my attending physician.

While being entitled to make decision and think straightly, Iaccept the medical procedure to be performed, and consent that my attending physician and his/her team will carry out any medical treatment option/surgical technique/intervention they deem to be necessary.

I authorize the hospital to examine, inspect, dispose of or keep the tissues or organs removed during the procedure for which I have consented above.

I allow my medical reports to be used for scientific researches provided that my identifying information is kept hidden.

I understand and accept that the procedure can be performed with the attendance of a medical school student, a specialist student of medicine and a physician making clinical observation under the supervision of a chief physician in Suleyman Demirel University and affiliated hospitals.

Please fill in the relevant fields by typing "I read, understood" with your handwriting.

Patient's			
Full Name:	Signature:	Date:	Time:
Date of Birth:			
Legal Representative's			
Full Name:			
Degree of Relationship	Signature	Date:	Time:

Reason why the consent is delivered by legal representative of the patient:					
Patient is not conscious	Patient is under 18		Other:		
Patient is not entitled to make decision	Emergency				
Witness'					
Full Name:					
Informing Physician's	Signature	Date:	Time:		
Full Name:					
Interpreter's (If required)	Signature	Date:	Time:		
Full Name:					

Informed consent is delivered by the patient himself/herself if s/he is older than 18 years old, by the patient himself/herself together with his/her legal representative if the patient is aged between 15 and 18 and by the representative of the patient if the patient is under 15 years old and/or is unconscious and/or is not entitled to make decision and in case of emergency.