



DR. JEFF C.H. DONOVAN
DERMATOLOGIST, SPECIALIZING IN HAIR LOSS

4370 Lorimer Road
Suite 334B
Whistler, BC, Canada
V8E 1A6

Tel: 604.283.1887
Fax: 604.648.9003
Email: office@donovanmedical.com
Web: www.donovanmedical.com

CONSENT FOR USE OF HYALURONIDASE TO TREAT CUTIS VERTICIS GYRATA (CVG)

A very limited number of studies support the off label use of hyaluronidase to treat CVG. This particular treatment is not formally FDA or Health Canada approved to treat CVG. In fact, there is no treatment formally FDA approved for this condition.

Hyaluronidase is most commonly used in aesthetic medicine to dissolve hyaluronic acid fillers when hyaluronic acid gets placed in areas that it was not intended.

Hyaluronidase rarely causes allergic reactions, including local allergic reaction and systemic allergic reaction like hives, angioedema and anaphylaxis. Fortunately, the latter are rare. Estimates suggest a rate of 1 in 1000.

In order to see if you have an increased risk of having an allergic reaction, a skin test on the forearm is sometimes performed first. A small amount of hyaluronic acid is injected into the arm and then the area is observed to see if any sort of allergic reaction happens in the skin of the forearm. If it does not, it is generally safe to proceed.

Patients with significant prior allergy to wasps and bees and insects and snake bites are not generally deemed candidates for hyaluronidase injections.

After the procedure, patients are monitored for 60 minutes in the office. If there are no concerns about allergic reactions, patients are given the okay to leave the office. Patients should still monitor for any signs of allergy through the day and get medical help/call 911 if such side effects occur. The symptoms of a severe allergic reaction can include swelling of the tongue, eyelids, lips, difficulty catching one's breath, wheezing, coughing, difficulty swallowing, hoarseness of the voice, stomach pain, nausea, vomiting or diarrhea.

CONSENT FOR HYALURONIC ACID INJECTIONS

1. I, _____, hereby give consent to **Dr. Jeff Donovan Medicine Professional Corporation** to perform hyaluronic acid injections into the scalp.

2. I declare that I have allergies to these medications:

3. I declare that I have NOT had allergies to bee or wasps, insects or snake bites.

4. I declare that I have NOT had allergies to hyaluronidase injections in the past.

5. I have declared that I take the following medications:

6. I have declared that I do not take the following medications (or have stopped for the past 7 days): ibuprofen, aspirin, NSAIDS, vitamin C, antihistamines, mast cell stabilizers (cromolyn), antioxidants

7. Prior to my consenting to hyaluronic acid injections, I have read the above information on hyaluronidase injections (page 1) and had my questions answered.

8. I declare that the fees were discussed with me in full and have agreed to pay these fees prior to the procedure.

9. I fully understand the results that I may reasonably expect and that not every patient is expected to get good results. An explanation of the procedure has been given to me. I understand that a "patch test session" will be performed on the forearm (along with a saline control) and if there is no allergy, a full session on the scalp will be performed. I understand that I will need to be monitored 60 minutes after the full procedure and agree to stay for that monitoring.

10. I am aware of the pros, cons and alternatives to these hyaluronidase injections. I understand that I have the opportunity not to pursue any treatment as generally this condition is not harmful to me. I know I have options to discuss surgical options with a plastic surgeon and to discuss use of fillers for the troughs.
11. I understand that this is a somewhat 'new' procedure and that not everything is known about how best to use hyaluronidase in treating CVG.
12. I understand that results are not guaranteed and that ongoing injections could be needed to maintain a good effect. I understand I may need hyaluronidase injections ongoing at various intervals through my life. I understand that fees charged in Dr. Donovan's office are for each session rather than a one-time flat fee for all injections.
13. I have been informed that hyaluronidase injections are generally a safe procedure; however I am aware that side effects may occur. The more common complications and a partial list of rare complications have been explained to me. A list of complications is outlined below:

SIDE EFFECTS AND COMPLICATIONS of HYALURONIDASE

- i. Skin infection (rare)
- ii. Allergic reactions and anaphylaxis (rare) – about 1 in 1000
 - The symptoms of a severe allergic reaction can include swelling of the tongue, eyelids, lips, difficulty catching one's breath, wheezing, coughing, difficulty swallowing, hoarseness of the voice, stomach pain, nausea, vomiting or diarrhea.
- iii. Pain/discomfort with injections and minor discomfort for 1-7 days after the procedure
- iv. Swelling and bruising and redness may occur
- v. Headaches
- vi. Temporary hair loss (rare)

I have read and understand all of the possible side effects and complications listed above. I accept the risks of these possible complications and consequences associated with this procedure. I consent to this procedure.

Patient Signature

Date

Physician Signature

Date

14. I consent to having my photos taken. These include pre-procedure ('before') photos, photos during the procedure ('during') and post-procedure ('after') photos. I understand these photos will not reveal my identity. I give consent to Dr. Donovan to use these photos in teaching and research, including teaching of doctors, students, trainees and the general public. I consent to having photos used for advertising purposes, which may include social media, websites and use during consultations with other patients. I understand that I may withdraw consent by stating 'no consent for sharing photos' on the line below. However, photos will still be obtained for my chart and for purposes of documentation of surgical outcomes.

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12. I believe that I have been well informed. I understand that good results are expected, but the practice of medicine is not an exact sciences. I understand that knowledgeable practitioners sometimes disagree as to the best methods of treatment to achieve desired results.
13. This consent was read and signed while I was not under the influence of medications that might alter my mental capacity to understand its contents.

- 14. I certify this form has been read or it has been read to me, and I understand its contents. I was given the opportunity to ask questions about this procedure
- 15. I have disclosed all information regarding past and present medical conditions, current medications and known drug allergies. This information is necessary so that the proper medical treatment is given at all times during the transplant procedure.
- 16. I have been given the opportunity by my physician to ask questions and all of my questions have been answered to my satisfaction. I impose the following limitations or restrictions on my treatment:

DATE: _____

TIME: _____ (am or pm)

Signature of Patient **Date**

Signature of Doctor **Date**

FINAL EXIT DECLARATION

I declare that I was treated today with _____ units of hyaluronidase. I had a patch test performed on my _____ forearm and I had no significant reaction. I was monitored for 60 minutes before leaving the office. I understand that I am to call 1.604.283.1887 if I have any general concerns or email office@donovanmedical.com

I understand if I have more immediate concerns or am worried, I am to call 911.

I was given a copy of this consent form and information.

DATE: _____ **TIME:** _____ (am or pm)

SIGNATURE OF PATIENT

FULL NAME OF PATIENT

TODAY'S DATE