dilution, number of injection sites, or distance between the injection sites for any BoNT product in the treatment of neuropathic pain.

OBJECT OF THE INVENTION

[0011] In view of the above, the object of the present invention is how to provide an improved treatment for peripheral neuropathic pain.

SUMMARY

[0012] The present disclosure relates to the use of botulinum toxin for the treatment of peripheral neuropathic pain. It was found that the use of a specific dosing and injection scheme for the administration of botulinum toxin is highly effective in the reduction of peripheral neuropathic pain while being well tolerable and safe.

[0013] In a first example, the present disclosure relates to a botulinum toxin for use in the treatment of peripheral neuropathic pain, wherein the botulinum toxin is subcutaneously injected into a skin area of a patient at a concentration of 35 U/ml to 65 U/ml, and at a dose of 4.0 U to 6.0 U per injection point and a volume of 0.07 ml to 0.15 ml per injection point, and wherein the distance between injection points is 1.5 cm to 2.5 cm.

[0013a] In an aspect, the present disclosure relates to use of a botulinum toxin in the manufacture of a medicament for the treatment of peripheral neuropathic pain, wherein the botulinum toxin is to be subcutaneously injected into a skin area of a patient at a concentration of 35 U/ml to 65 U/ml, and at a dose of 4.0 U to 6.0 U per injection point and a volume of 0.07 ml to 0.15 ml per injection point, and wherein the distance between injection points is 1.5 cm to 2.5 cm.

[0014] The peripheral neuropathic pain is preferably selected from the group consisting of post-herpetic neuralgia (PHN), peripheral nerve injury (e.g., due to surgery or trauma), trigeminal neuralgia, painful polyneuropathy (e.g., diabetic neuropathic pain (DNP)), and painful radiculopathy. Within the present

disclosure, the PNP is particularly preferred post-herpetic neuralgia (PHN), PNP due to peripheral nerve injury, in particular peripheral nerve injury due to surgery or peripheral nerve injury due to trauma, or painful polyneuropathy, in particular diabetic neuropathic pain (DNP).

[0015] In the context of the present disclosure, the botulinum toxin is preferably of type A. Further, the botulinum toxin may be in a form that is free of complexing proteins

or is in the form of a complex that contains complexing proteins. Preferably, the botulinum toxin is of type A and in a form that is free of complexing proteins or, in an alternative preferred example, is of type A and in the form of a complex that contains complexing proteins.

[0016] In a second example, the present disclosure relates to a method for the treatment of peripheral neuropathic pain, the method comprising administering an effective amount of botulinum toxin by subcutaneous injection into a skin area of a patient at a concentration of 35 U/ml to 65 U/ml, and at a dose of 4.0 U to 6.0 U per injection point and a volume of 0.07 ml to 0.15 ml per injection point, and wherein the distance between injection points is 1.5 cm to 2.5 cm.

[0017] Preferred embodiments are set forth in the appended dependent claims and in the following detailed description.

DETAILED DESCRIPTION OF THE INVENTION

[0018] The present invention provides a specific dosing and injection scheme that results in beneficial treatment effects of BoNT injections on peripheral neuropathic pain. The BoNT dosing and injection scheme is not only highly efficient in reducing PNP and symptoms associated therewith but is also well tolerated and safe. The BoNT is locally injected into painful skin areas. It is a minimally invasive treatment modality that has only minimal side effects. Compared to commonly prescribed systemic drugs, the local injection treatment with BoNT does not have prevalent side effects (e.g., dry mouth, nausea and sleepiness) and does not involve the problem of opioid misuse and addiction. Thus, in terms of efficacy, safety, and tolerability, the specific local injection treatment with BoNT according to the present invention is a favourable therapeutic approach for the treatment of peripheral neuropathic pain.

[0019] The mentioned advantages are the result of a specific combination of different aspects of administration, including route of administration (subcutaneous injections), distance between injection sites (preferably 2 cm), dose of BoNT per injection site (preferably 5 U), concentration (preferably 50 U BoNT per 1 mL), total

CLAIMS

1. Use of a botulinum toxin in the manufacture of a medicament for the treatment of peripheral neuropathic pain, wherein the botulinum toxin is to be subcutaneously injected into a skin area of a patient at a concentration of 35 U/ml to 65 U/ml, and at a dose of 4.0 U to 6.0 U per injection point and a volume of 0.07 ml to 0.15 ml per injection point, and wherein the distance between injection points is 1.5 cm to 2.5 cm.

2. The use according to claim 1, wherein the volume per injection point is 0.08 ml to 0.13 ml.

3. The use according to claim 1 or 2, wherein the dose per injection point is 4.5 U to 5.5 U.

4. The use according to claim 1 or 2, wherein the concentration is 40 U/ml to 60 U/ml.

5. The use according to claim 4, wherein the dose per injection point is 4.5 U to 5.5 U and the volume per injection point is 0.07 ml to 0.14 ml.

6. The use according to claim 5, wherein the volume per injection point is 0.08 ml to 0.13 ml.

7. The use according to any one of claims 1 to 6, wherein the distance between injection points is 1.8 cm to 2.2 cm.

8. The use according to any one of claims 1 to 7, wherein the total dose is up to 400 U or the total number of injection points is up to 90, or wherein the total dose is up to 400 U and the total number of injection points is up to 90.

9. The use according to claim 8, wherein the total dose is between 100 U and 400 U or up to 300 U or between 200 U and 300 U or from more than 300 U to 400 U

or the total number of injection points is 40 to 90 or 50 to 90 or up to 80 or 50 to 80 or 60 to 80, or wherein the total dose is between 100 U and 400 U or up to 300 U or between 200 U and 300 U or from more than 300 U to 400 U and the total number of injection points is 40 to 90 or 50 to 90 or up to 80 or 50 to 80 or 60 to 80

10. The use according to any one of claims 1 to 9, wherein the injection points are arranged in a grid pattern including a quadrangular grid, a rectangular grid with each of the four injection points forming a rectangle being equally spaced from each other, and a square grid.

11. The use according to any one of claims 1 to 10, wherein the peripheral neuropathic pain is selected from the group consisting of post-herpetic neuralgia, peripheral nerve injury, trigeminal neuralgia, painful polyneuropathy, and painful radiculopathy.

12. The use according to claim 11, wherein the peripheral neuropathic pain is post-herpetic neuralgia, peripheral nerve injury or painful polyneuropathy including diabetic neuropathic pain.

13. The use according to any one of claims 1 to 12, wherein the botulinum toxin is of type A.

14. The use according to any one of claims 1 to 13, wherein the botulinum toxin is in a form that is free of complexing proteins or is in the form of a complex that contains complexing proteins.