CLAIMS

1. A method for the treatment of bone marrow edema lesions as assessed by magnetic resonance imaging (MRI) in a mammal, the method comprising the step of administering a polysulfated polysaccharide or an acceptable salt thereof, to a mammal in need of such treatment.

2. Use of a polysulfated polysaccharide or an acceptable salt thereof, in the treatment of bone marrow edema lesions as assessed by magnetic resonance imaging (MRI) in a mammal.

3. Use of a polysulfated polysaccharide or an acceptable salt thereof, in the manufacture of a medicament for the treatment of bone marrow edema lesions as assessed by magnetic resonance imaging (MRI) in a mammal.

4. The method according to any one of claims 1 to 3, wherein the mammal is suffering from osteoarthritis.

5. The method according to claim 4, wherein the osteoarthritis is in an articulating joint selected from the group consisting of: an ankle, a hip, knee, shoulder, spine (spondylosis) and wrist.

6. A method for the treatment of Modic Endplate Changes Type I in the spine of a mammal as assessed by magnetic resonance imaging (MRI), the method comprising the step of administering a polysulfated polysaccharide or an acceptable salt thereof, to a mammal in need of such treatment.

7. Use of a polysulfated polysaccharide or an acceptable salt thereof, in the treatment of Modic Endplate Changes Type I in the spine of a mammal as assessed by magnetic resonance imaging (MRI).

8. Use of a polysulfated polysaccharide or an acceptable salt thereof, in the manufacture of a medicament for the treatment of Modic Endplate Changes Type I in the spine of a mammal as assessed by magnetic resonance imaging (MRI).

9. A method for the treatment of back pain in a mammal with Modic Endplate Changes Type I in the spine as assessed by magnetic resonance imaging (MRI), the method comprising the step of administering a polysulfated polysaccharide or an acceptable salt thereof, to a mammal in need of such treatment.

10. Use of a polysulfated polysaccharide or an acceptable salt thereof, in the treatment of back pain in a mammal with Modic Endplate Changes Type I in the spine as assessed by magnetic resonance imaging (MRI).

11. Use of a polysulfated polysaccharide or an acceptable salt thereof, in the manufacture of a medicament for the treatment of back pain in a mammal with Modic Endplate Changes Type I in the spine as assessed by magnetic resonance imaging (MRI).

12. The method according to claim 9 or the use according to claim 10 or claim 11, wherein the back pain is selected from the group consisting of: general back pain, acute back pain, chronic back pain, general low back pain, acute low back pain and chronic low back pain.

13. The method according to claim 6 or claim 9 or the use according to any one of claims 7, 8, 10 or 11, wherein the Modic Endplate Changes Type I in the spine are associated with Modic Endplate Changes Type II in the spine.

14. The method according to claim 6 or claim 9 or the use according to any one of claims 7, 8, 10 or 11, wherein the Modic Endplate Changes Type I in the spine are associated with Modic Endplate Changes Type III in the spine.

15. The method or the use according to any one of claims 1 to 14, wherein the polysulfated polysaccharide is selected from the group consisting of high molecular weight heparin, low molecular weight heparins, the heparan sulfates, pentosan polysulfate, chondroitin polysulfate, chitosan polysulfate, dermatan polysulfate sulodexide, dextran sulfate, polysulfated inulin, sulfated lactobionic acid amide, sulfated bis-aldonic acid amide, sucrose octasulfate, fucoidan-1, fucoidan-2, sulfated beta-cyclodextrin, sulfated gamma-cyclodextrin and small sulfated compounds including, but are not limited to, inositol hexasulfate.

16. The method or the use according to claim 15, wherein the polysulfated polysaccharide is selected from the group consisting of high molecular weight heparin, low molecular weight heparins, pentosan polysulfate (PPS), chondroitin polysulfate and chitosan polysulfate.

17. The method or the use according to claim 16, wherein the pentosan polysulfate (PPS) is selected from the group consisting of: the sodium salt of pentosan polysulfate (NaPPS), the magnesium salt of pentosan polysulfate (MgPPS), the calcium salt of pentosan polysulfate (CaPPS), and the zinc salt of pentosan polysulfate (ZnPPS).

18. The method or the use according to claim 17, wherein the pentosan polysulfate (PPS) is sodium pentosan polysulfate (NaPPS).

19. The method or the use according to any one of claims 1 to 18, wherein treatment is by administering an injection by the intra-muscular (IM) or sub-cutaneous (SC) routes, intra-venously (IV), intra-articularly (IA), peri-articularly, topically, via suppositories or orally.

20. The method or the use according to any one of claims 1 to 19, wherein the treatment is by administering the polysulfated polysaccharide or the acceptable salt thereof to the mammal in an effective amount of about 1 to 2 mg/kg of the mammal per dose or an effective amount of between about 25 mg and 300 mg as a fixed dose.

21. The method or the use according to any one of claims 1 to 20, wherein the treatment is by administering the polysulfated polysaccharide or the acceptable salt thereof to the mammal in an effective amount of about 2 mg/kg of the mammal per dose or an effective amount of about 150 mg as a fixed dose.

22. The method or the use according to any one of claims 19 to 21, wherein the treatment is by administering a sub-cutaneous (SC) injection.

23. The method or the use according to claim 22, wherein the SC injection is a slow SC injection.

24. The method or the use according to any one of claims 19 to 23, wherein administration to a human is by dosing in a treatment regimen once daily, twice weekly or thrice weekly.

25. The method or the use according to claim 24, wherein administration to a human is by dosing in a treatment regimen twice weekly.

26. The method or the use according to claim 25, wherein administration to a human is by dosing in a treatment regimen twice weekly with a minimum of three days and a maximum of four days between dosages.

27. The method or the use according to claim 26, wherein administration to a human is by dosing in a treatment regimen twice weekly for six weeks.

28. The method or the use according to any one of claims 19 to 27, wherein the total dose of polysulfated polysaccharide administered in the treatment regimen is about 200 to 4000 mg.

29. The method or the use according to any one of claims 1 to 28, wherein pain in the mammal is reduced after treatment.

30. The method or the use according to claim 29, wherein pain in the mammal is reduced as determined by the numerical rating scale (NRS).

31. The method or the use according to any one of claims 1 to 30, wherein function in the mammal is improved after treatment.

32. The method or the use according to claim 31, wherein the function in the mammal is improved as determined by the Lysholm Knee Score described herein.

33. The method or the use according to any one of claims 1 to 32, wherein the presence of bone marrow edema lesions or Modic Endplate Changes is reduced as assessed by magnetic resonance imaging.

34. The method or the use according to any one of claims 1 to 32, wherein the presence of bone marrow edema lesions or Modic Endplate Changes is resolved as assessed by magnetic resonance imaging.

CLAIMS

1. Use of pentosan polysulfate or an acceptable salt thereof in the preparation of an intramuscular medicament for improving knee function in a human having bone marrow edema lesions in the knee as assessed by magnetic resonance imaging (MRI) and osteoarthritis 3-4 on the Kellgren-Lawrence scale in the knee so as to improve knee function by about 23% to about 89% as determined by the Lysholm Knee Score, wherein it has been determined that treatment of the knee of the human with a corticosteroid has failed.

2. The use of claim 1, wherein knee function is improved by about 23% to about 43%.

3. The use of claim 2, wherein knee function is improved by about 23% to about 35%.

4. The use according to any one of claims 1 to 3, wherein the pentosan polysulfate (PPS) is selected from the group consisting of: the sodium salt of pentosan polysulfate (NaPPS), the magnesium salt of pentosan polysulfate (MgPPS), the calcium salt of pentosan polysulfate (CaPPS), and the zinc salt of pentosan polysulfate (ZnPPS).

5. The use according to claim 4, wherein the pentosan polysulfate (PPS) is sodium pentosan polysulfate (NaPPS).

6. The use according to any one of claims 1 to 5, wherein the medicament comprises pentosan polysulfate or the acceptable salt thereof in an effective amount of about 1 to 2 mg/kg of the human per dose or an effective amount of between about 25 mg and 300 mg as a fixed dose.

7. The use according to any one of claims 1 to 6, wherein the medicament comprises pentosan polysulfate or the acceptable salt thereof in an effective amount of

about 2 mg/kg of the human per dose or an effective amount of about 150 mg as a fixed dose.