reconcentration of the plasma. *Id* at 619.

[7] A treatment regime in which periodic plasmapheresis, requiring smaller volumes than traditional therapeutic plasmapheresis, shorter duration time and a single venipuncture that reduces LDL levels in patients having abnormal LDL levels and/or increases HDL levels in patients having abnormal HDL levels would be desirable.

Summary of Selected Features

[7a] In one aspect, there is provided whole blood cells without plasma, the plasma being separated from the whole blood cells by extracorporeal plasmapheresis, for use in the treatment of cholesterol disorders, wherein said whole blood cells are administered to a patient having abnormal total cholesterol, abnormal LDL levels and/or abnormal HDL levels when measured before treatment, in a first treatment regime comprising two or more rounds, wherein the first treatment regime decreases LDL levels in patients having abnormal LDL levels and/or increases HDL levels in patients having abnormal HDL levels and wherein each subsequent round of the first treatment regime maintains the new, lower total cholesterol level, lower LDL level, and/or higher HDL level.

[7b][~~7a~~] In another~~a first~~ aspect, there is provided the use of whole blood cells without plasma, wherein the plasma is separated from the whole blood cells by plasmapheresis, in the manufacture of a medicament for treating cholesterol disorders,

wherein the medicament is for administration as a first treatment regime comprising two or more rounds of plasmapheresis to a patient having abnormal total cholesterol, abnormal LDL levels and/or abnormal HDL levels when measured before treatment, wherein the first treatment regime decreases LDL levels in patients having abnormal LDL levels and/or increases HDL

levels in patients having abnormal HDL levels and

wherein each subsequent round of the first treatment regime maintains the new, lower total cholesterol level, lower LDL level, and/or higher HDL level.

[7c][~~7b~~] In another~~a second~~ aspect, there is provided a system comprising:

a) a composition which consists of whole blood cells with out plasma, the plasma being separated from the whole blood cells by plasmapheresis; and

b) a device comprising:

a housing;

an entrance port for receiving whole blood from a donor;

means for separating plasma from the cellular components of the whole blood; and

means for returning the cellular components of the blood to the donor.

[7d]~~[7c]~~ In another~~a third~~ aspect, there is provided a device comprising:

a housing;

an entrance port for receiving whole blood from a donor;

means for separating plasma from the cellular components of the whole blood; and

means for returning the cellular components of the blood to the donor.

[7e]~~[7d]~~ In another~~a fourth~~ aspect, there is provided a use of whole blood cells without plasma, in the manufacture of a medicament for treating cholesterol disorders.

[8] There is also provided a method of treating patients suffering from cholesterol disorders includes administering a first treatment regime comprising two or more rounds of plasmapheresis to a patient having abnormal total cholesterol levels, abnormal LDL levels and/or abnormal HDL levels when measured prior to treatment. The method decreases LDL levels in patients having abnormal LDL levels and increases HDL levels in patients having abnormal HDL levels. The subsequent round of plasmapheresis could be conducted about 2 to about 14 days after a previous round of plasmapheresis. For example, a first round occurring on day 1 could be followed up by a second round on day 4, the third round on day 8, and the fourth round could be on day 11.

Brief Description of the Drawings

[9] Figure 1 is a device to be used in the method of the present invention.

[10] Figure 2 is a diagram illustrating the separation process from whole blood.

We Claim:

1. Use of whole blood cells without plasma, wherein the plasma is separated from the whole blood cells by plasmapheresis, in the manufacture of a medicament for treating cholesterol disorders,

wherein the medicament is for administration as a first treatment regime comprising two or more rounds of plasmapheresis to a patient having abnormal total cholesterol, abnormal LDL levels and/or abnormal HDL levels when measured before treatment, wherein the first treatment regime decreases LDL levels in patients having abnormal LDL levels and/or increases HDL levels in patients having abnormal HDL levels and

wherein each subsequent round of the first treatment regime maintains the new, lower total cholesterol level, lower LDL level, and/or higher HDL level.

2. The use of Claim 1, wherein each subsequent round of the first treatment regime is conducted about 2 to about 4 days after the previous round.

3. The use of Claim 1, wherein each subsequent round of the first treatment regime is conducted about 5 to about 9 days after the previous round.

4. The use of Claim 1, wherein each subsequent round of the first treatment regime is conducted about 10 to about 14 days after the previous round.

5. The use of Claim 1, wherein at least one statin is to be administered to the patient before, during and/or after the first treatment regime.

6. The use of Claim 1, wherein the medicament further comprises a saline solution.

7. The use of Claim 1, wherein each round of the first treatment regime comprises low-volume plasmapheresis in which less than about 1000 mL of blood is treated.

8. The use of Claim 1, wherein the first treatment regime reduces LDL levels in patients having abnormal LDL levels prior to the first treatment regime by about 5 mg/dL to about 45 mg/dL.

9. The use of Claim 8, wherein the first treatment regime reduces LDL levels in patients having abnormal LDL levels prior to the first treatment regime by about 10 mg/dL to about 35 mg/dL.

10. The use of Claim 1, wherein the first treatment regime increases HDL levels in patients having abnormal HDL levels prior to the first treatment regime by about 1 mg/dL to about 5 mg/dL.

11. The use of Claim 10, wherein the first treatment regime increases HDL levels in patients having abnormal HDL levels prior to the first treatment regime by about 2 mg/dL to about 4 mg/dL.

12. The use of Claim 1, wherein the first treatment regime lasts for at least about 2 weeks or

more.

13. The use of Claim 1, wherein repeated plasmapheresis is to be administered to maintain the lower total cholesterol and LDL levels and/or higher HDL levels.

14. The use of Claim 1, wherein the first treatment regime is to be tailored based on the total cholesterol, LDL, and/or HDL levels of the patient.

15. A system comprising:

a) a composition which consists of whole blood cells with out plasma, the plasma being separated from the whole blood cells by plasmapheresis; and

b) a device comprising:

a housing;

an entrance port for receiving whole blood from a donor;

means for separating plasma from the cellular components of the whole blood; and

means for returning the cellular components of the blood to the donor.

16. The system of Claim 15, wherein said whole blood cells composition comprises at least one statin.

17. The system of Claim 15, wherein said whole blood cell composition further comprises a saline solution.

18. The system of Claim 15, wherein said means for separating plasma from the cellular components of the blood are centrifugation means.

19. The system of Claim 15, wherein said means for separating plasma from the cellular components of the blood are filtration means.

20. The system of Claim 15, wherein said means for returning the cellular components of the blood comprise a catheter.

21. A device comprising:

a housing;

an entrance port for receiving whole blood from a donor;

means for separating plasma from the cellular components of the whole blood; and

means for returning the cellular components of the blood to the donor.

22. The device of claim 21 further comprising a composition which consists of whole blood cells with out plasma, the plasma being separated from the whole blood cells by plasmapheresis.

23. The device of Claim 22, wherein said whole blood cells composition comprises at least one statin.

24. The device of Claim 22, wherein said whole blood cell composition further comprises a saline solution.

25. The device of Claim 21, wherein said means for separating plasma from the cellular components of the blood are centrifugation means.

26. The device of Claim 21, wherein said means for separating plasma from the cellular components of the blood are filtration means.

27. The device of Claim 21, wherein said means for returning the cellular components of the blood comprise a catheter.

28. Use of whole blood cells without plasma, in the manufacture of a medicament for treating cholesterol disorders.

We Claim:

1. Whole blood cells without plasma, the plasma being separated from the whole blood cells by extracorporeal plasmapheresis, for use in the treatment of cholesterol disorders, wherein said whole blood cells are administered to a patient having abnormal total cholesterol, abnormal LDL levels and/or abnormal HDL levels when measured before treatment, in a first treatment regime comprising two or more rounds, wherein the first treatment regime decreases LDL levels in patients having abnormal LDL levels and/or increases HDL levels in patients having abnormal HDL levels and wherein each subsequent round of the first treatment regime maintains the new, lower total cholesterol level, lower LDL level, and/or higher HDL level.

2. Whole blood cells for use according to Claim 1, wherein each subsequent round of the first treatment regime is conducted about 2 to about 4 days after the previous round.

3. Whole blood cells for use according to Claim 1, wherein each subsequent round of the first treatment regime is conducted about 5 to about 9 days after the previous round.

4. Whole blood cells for use according to Claim 1, wherein each subsequent round of the first treatment regime is conducted about 10 to about 14 days after the previous round.

5. Whole blood cells for use according to Claim 1, wherein the first treatment regime includes the use of at least one statin before, during and/or after said first treatment regime.

6. Whole blood cells for use according to Claim 1, further comprising a saline solution.

7. Whole blood cells for use according to Claim 1, wherein the volume of blood treated in each round of the first treatment regime to obtain said whole blood cells is less than about 1000 mL.

8. Whole blood cells for use according to Claim 1, wherein the first treatment regime reduces LDL levels in patients having abnormal LDL levels prior to the first treatment regime by about 5 mg/dL to about 45 mg/dL.

9. Whole blood cells for use according to Claim 8, wherein the first treatment regime reduces LDL levels in patients having abnormal LDL levels prior to the first treatment regime by about 10 mg/dL to about 35 mg/dL.

10. Whole blood cells for use according to Claim 1, wherein the first treatment regime increases HDL levels in patients having abnormal HDL levels prior to the first treatment regime by about 1 mg/dL to about 5 mg/dL.

11. Whole blood cells for use according to Claim 10, wherein the first treatment regime increases HDL levels in patients having abnormal HDL levels prior to the first treatment regime by about 2 mg/dL to about 4 mg/dL.

12. Whole blood cells for use according to Claim 1, wherein the first treatment regime lasts for at least about 2 weeks or more.

13. Whole blood cells for use according to Claim 1, further including tailoring the first treatment regime based on the total cholesterol, LDL, and/or HDL levels of the patient.