[0006] However, many of these treatments are recommended for acute conditions and do not address or provide for a long-term reduction in cardiovascular events in patients with clinically stable atherosclerotic vascular disease.

[0007] It is against this background that the present invention has been developed.

[0008] The present invention seeks to overcome, or at least ameliorate, one or more of the deficiencies of the prior art mentioned above, or to provide the consumer with a useful or commercial choice.

SUMMARY

[0009] In one aspect, there is provided use of a therapeutically effective amount of a composition comprising about 0.6 total mg of colchicineor a salt thereof , in the manufacture of a medicament for treating and/or preventing a cardiovascular event in a subject with atherosclerotic vascular disease, wherein the cardiovascular event is acute coronary syndrome, out-of-hospital cardiac arrest, or noncardioembolic ischemic stroke, and wherein the medicament is formulated for use once per day.

[0009a] In another aspect, there is provided use of a therapeutically effective amount of a composition comprising no more than about 0.6 total mg of colchicineor a salt thereof , in the manufacture of a medicament for treating and/or preventing cholesterol crystal-induced inflammation within atherosclerotic plaques in a subject having, or having a previous history of, atherosclerotic vascular disease, wherein the medicament is formulated for use once per day.

[0009b] In yet another aspect, there is provided use of a therapeutically effective amount of a composition comprising no more than about 0.6 total mg of colchicine or a salt thereof or any combination thereof, in the manufacture of a medicament for treating and/or preventing a cardiovascular event in patients with atherosclerotic vascular disease.

[0009c] In a further aspect, there is provided use of a therapeutically effective amount of a composition comprising no more than about 0.6 total mg of colchicineor a salt thereof , or any combination thereof, in the manufacture of a medicament for treating and/or preventing a cardiovascular event in a patient undergoing co-administration of a second agent for the treatment and/or prevention of an atherosclerotic vascular disease, wherein the cardiovascular event is acute coronary syndrome, out-of-hospital cardiac arrest, or noncardioembolic ischemic stroke, and wherein the medicament is formulated for use once per day.

[0009d] The present disclosure also provides a method for the treatment or prevention of a cardiovascular event in a subject comprising the step of:

administering a therapeutically effective amount of a compound of formula (I), a known colchicine derivative and/or a salt thereof.

[0010] The present disclosure also provides a method for the treatment or prevention of a cardiovascular event in a subject with atherosclerotic vascular disease comprising the step of:

administering a therapeutically effective amount of a compound of formula (I), a known colchicine derivative and/or a salt thereof.

[0011] The present disclosure further provides a method for the treatment or prevention of a cardiovascular event in a subject with atherosclerotic vascular disease comprising the step of:

administering a therapeutically effective amount of a compound of formula (I), a known colchicine derivative and/or a salt thereof and one or more additional agents selected from the list comprising: a statin and/or an anti-platelet agent.

[0012] In one example, the atherosclerotic vascular disease is a coronary disease. The coronary disease may be stable or unstable.

[0013] The present disclosure further provides a method for the treatment or prevention of a cardiovascular event in a subject comprising the step of:

administering a therapeutically effective amount of a compound of formula (I), a known colchicine derivative and/or a salt thereof

wherein the subject has coronary disease prior to administration of the therapeutically effective amount of a compound of formula (I), a known colchicine derivative and/or a salt thereof. Preferably the coronary disease is a stable coronary disease.

[0014] The present disclosure further provides a method for reducing or preventing cholesterol crystal induced inflammation within atherosclerotic plaques in a subject, comprising the step of

administering a dosage of 0.5 mg or 0.6 mg of a compound of formula (I), a known colchicine derivative and/or a salt thereof.

CLAIMS

1. Use of a therapeutically effective amount of a composition comprising about 0.6 total mg of colchicine or a salt thereof, in the manufacture of a medicament for treating and/or preventing a cardiovascular event in a subject with atherosclerotic vascular disease, wherein the cardiovascular event is acute coronary syndrome, out-of-hospital cardiac arrest, or noncardioembolic ischemic stroke, and wherein the medicament is formulated for use once per day.

2. The use of claim 1, wherein the treatment and/or prevention of the cardiovascular event further comprises a second agent to be co-administered for the treatment and/or prevention of the cardiovascular event in the subject.

3. Use of a therapeutically effective amount of a composition comprising no more than about 0.6 total mg of colchicine or a salt thereof, in the manufacture of a medicament for treating and/or preventing cholesterol crystal-induced inflammation within atherosclerotic plaques in a subject having, or having a previous history of, atherosclerotic vascular disease, wherein the medicament is formulated for use once per day.

4. The use of claim 3, wherein the composition reduces or prevents cholesterol crystal induced inflammation within atherosclerotic plaques.

5. Use of a therapeutically effective amount of a composition comprising no more than about 0.6 total mg of colchicine or a salt thereof, or any combination thereof, in the manufacture of a medicament for treating and/or preventing a cardiovascular event in patients with atherosclerotic vascular disease.

6. The use of claim 5, wherein the atherosclerotic vascular disease is a coronary disease.

7. The use of claim 6, wherein the coronary disease is a clinically stable coronary disease.

8. The use of any one of claims 1 to 7, wherein the composition is to be administered orally, topically, parenterally, intraorbitally, ophthalmically, intraventricularly, intracranially, intracapsularly, intraspinally, intracisternally, intraperitoneally, buccally, rectally, vaginally, intranasally, or by aerosol administration, and/or inhalation spray, or via an implanted reservoir.

9. The use of any one of claims 1 to 8, wherein the composition is to be administered in the form of a tablet, capsule, liquid dose, gel, or powder.

10. Use of a therapeutically effective amount of a composition comprising no more than about 0.6 total mg of colchicine or a salt thereof, or any combination thereof, in the manufacture of a medicament for treating and/or preventing a cardiovascular event in a patient undergoing co-administration of a second agent for the treatment and/or prevention of an atherosclerotic vascular disease, wherein the cardiovascular event is acute coronary syndrome, out-of-hospital cardiac arrest, or noncardioembolic ischemic stroke, and wherein the medicament is formulated for use once per day.

11. The use of claim 10, wherein the second agent is a statin.

12. The use of claim 11, wherein the statin is selected from the group consisting of atorvastatin, rosuvastatin, simvastatin, fluvastatin, lovastatin, pitavastatin, rosuvastatin and pravastatin, or a salt thereof.

13. The use of claim 10, wherein the second agent is an anti-platelet agent.

14. The use of claim 13, wherein the anti-platelet agent is selected from the group consisting of irreversible cyclooxygenase inhibitors; adenosine diphosphate (ADP) receptor inhibitors; phosphodiesterase inhibitors; glycoprotein IIB/IIIA inhibitors;

adenosine reuptake inhibitors; thromboxane inhibitors; and Thromboxane receptor antagonists.

15. The use of any one of claims 1 to 14, wherein the composition comprises a pharmaceutically acceptable carrier, diluent, or excipient.