SUMMARY

As corroborated by the experimental section, which illustrates certain representative embodiments of the present disclosure, the inventors have realised that mesenchymal stem cells (MSC) or MSC-derived cells subjected to non-cryogenic suspension storage in liquid storage media based on human plasma or human serum displayed advantageous cell product viability and stability, even after storage for extended time periods. The present findings are unexpected, *inter alia* because equine plasma and serum have been reported as less satisfactory than a number of other liquid media, most prominently physiological saline, for suspension storage of horse MSC for 24 hours, and because cryopreservation has in any event been recommended for longer storage periods of the horse MSC (Garvican et al.).

Accordingly, the present disclosure provides a method for *in vitro* preservation of cells comprising maintaining adherent mesenchymal stem cells (MSC) or adherent MSC-derived cells in suspension in a composition comprising at least 20% v/v human plasma or human serum or a mixture thereof. Preferably, the present disclosure provides a method for non-cryogenic *in vitro* preservation of cells comprising maintaining adherent MSC or adherent MSC-derived cells in suspension in a composition comprising at least 20% v/v human plasma or human serum or a mixture thereof.

In one aspect of the present disclosure, there is provided a method for non-cryogenic *in vitro* preservation of cells comprising maintaining adherent mesenchymal stem cells (MSC) or adherent MSC-derived cells in suspension in a composition comprising at least 20% v/v human plasma or human serum or a mixture thereof, wherein the composition is maintained at between about 0.1°C and about 25°C.

The above and preferred embodiments of the present disclosure are described in the following sections and in the appended claims. The subject matter of appended claims is hereby specifically incorporated in this specification.

BRIEF DESCRIPTION OF DRAWINGS

Fig. 1 illustrates the proportion of living cells in a population of human MSC-derived osteoblastic cells after suspension storage at 2-8°C in the indicated storage media for 24, 48, 72, 96, 144 or 192 hours. NA (in this and subsequent figures): not available. "Standard excipient" (in this and subsequent figures): Plasma-Lyte® supplemented with 5% w/v HSA; "Plasma" (in this and subsequent figures): 100% Octaplas®; "Serum" (in this and subsequent figures): 100%, autoserum; HSA-enriched serum: Autoserum supplemented with 50% w/v human serum albumin (HSA).

CLAIMS

1. A method for non-cryogenic *in vitro* preservation of cells comprising maintaining adherent mesenchymal stem cells (MSC) or adherent MSC-derived cells in suspension in a composition comprising at least 20% v/v human plasma or human serum or a mixture thereof, wherein the composition is maintained at between about 0.1°C and about 25°C.

2. The method according to claim 1, comprising:

a) providing the composition comprising (i) the MSC or MSC-derived cells and (ii) the human plasma or human serum or the mixture thereof, optionally wherein said providing comprises a1) collecting the MSC or MSC-derived cells and a2) suspending the MSC or MSC-derived cells with at least the human plasma or human serum or the mixture thereof; and

b) maintaining the composition, so as to effect preservation of the cells.

3. The method according to any one of claims 1 or 2, wherein the composition is maintained at between 0.1°C and 25°C.

4. The method according to any one of claims 1 or 2, wherein the composition is maintained at between 2°C and 8°C.

5. The method according to any one of claims 1 to 4, wherein the composition is maintained for at least 24 hours, or for at least 30 hours, or for at least 36 hours, or for at least 42 hours, or for at least 48 hours, or for at least 72 hours, or for at least 96 hours, or for at least 120 hours, or for at least 144 hours, or for at least 168 hours, or for at least 192 hours.

6. The method according to claim 5, wherein the composition is maintained for at least 48 hours, preferably for at least 72 hours, more preferably for at least 96 hours, even more preferably for at least 120 hours, such as for at least 144 hours, or for at least 168 hours, or for at least 192 hours.

7. The method according to any one of claims 1 to 6, wherein the composition is maintained at between 2°C and 8°C for at least 48 hours, preferably for at least 72 hours, more preferably for at least 96 hours, even more preferably for at least 120 hours, such as for at least 144 hours, or for at least 168 hours, or for at least 192 hours.

8. The method according to any one of claims 1 to 7, wherein the source of human plasma is fresh plasma, freeze-dried plasma, solvent/detergent-treated plasma, fresh frozen plasma, thawed plasma, or cryoprecipitate, cryosupernatant or plasma concentrate such as concentrate from frozen plasma, or a mixture of any two or more thereof, or wherein the human serum is fresh serum, thawed frozen serum, or serum prepared from plasma, or a mixture of any two or more thereof.

9. The method according to any one of claims 1 to 8, wherein the composition remains liquid all through said maintaining of the composition.

10. The method according to any one of claims 1 to 9, wherein the concentration of the human plasma or human serum or the mixture thereof in the composition is at least 50% v/v, preferably at least 60% v/v, more preferably at least 70% v/v, even more preferably at least 80% v/v, still more preferably at least 90% v/v, yet more preferably at least 99-100% v/v.

11. The method according to any one of claims 1 to 10, wherein the concentration of the MSC or MSC-derived cells in the composition is between 1×10^4 and 1×10^{11}, or between 1×10^5 and 1×10^{10}, or between 1×10^6 and 1×10^9, or between 1×10^7 and 1×10^8, or between 2×10^7 and 5×10^7, such as 2.5×10^7 cells per mL of the composition.

12. The method according to any one of claims 1 to 11, wherein the composition consists essentially of or consists of i) the MSC or MSC-derived cells and ii) the human plasma or human serum or the mixture thereof.

13. The method according to any one of claims 1 to 11, wherein the composition is further supplemented with one or more fractionated components of plasma or serum, preferably wherein the composition is supplemented with human serum albumin (HSA).

14. The method according to any one of claims 1 to 13, wherein the MSC-derived cells comprise osteoprogenitors, osteoblastic cells, osteocytes, chondroblastic cells, chondrocytes, fibroblastic cells, fibroblasts, fibrocytes, tenoblasts, tenocytes, or synoviocytes.

15. The method according to any one of claims 1 to 14, wherein the MSC or MSC-derived cells are human MSC or MSC-derived cells.