Claims

1. A method for diagnosing and/or prognosing cancer, comprising
determining the level of at least one myeloid-derived suppressor cell (MDSC) phenotype in an MDSC population in a biological sample obtained from a patient based on at least one MDSC phenotype marker,
wherein said marker is selected from the group consisting of CD15; IL4Ra; CD14; CD11b; HLA-DR; CD33; Lin; FSC; SSC; and, optionally CD45; CD18; CD80; CD83; CD86; HLA-I; Live/Dead discriminator; and
wherein an increase of the level of said MDSC phenotypes compared to a non-cancer patient sample is indicative for cancer and/or a prognostic indicator for a treatment of said cancer.

2. The method according to claim 1, wherein said cancer is selected from renal cell carcinoma (RCC), colorectal cancer (CRC), gastric cancer (GC), melanoma, and adenocarcinoma.

3. The method according to claim 1 or 2, wherein said MDSC phenotype is selected from MDSC1 based on markers IL4Ra+ and CD14+; MDSC2 based on markers IL4Ra+ and CD15+; MDSC1 or 2 based on marker IL4Ra+; MDSC3 based on markers Lin-, HLA-DR-, and CD33+, optionally together with CD18+ and HLAI+; MDSC4 based on markers CD14+; HLA-DR(-/lo); FSChi; and SSCim; MDSC5 based on markers CD11b+; CD14-; CD15+; optionally together with FSChi; SSCim; CD80-; CD83-; CD86-; and HLA-DR-; and MDSC6 based on CD15+; FSClo; and SSChi.

4. The method according to any of claims 1 to 3, wherein said method comprises flow cytometry comprising a single multicolor staining step.

5. The method according to any of claims 1 to 4, further comprising a prognosis of a treatment, wherein an increased level of said MDSC phenotypes compared to pre-treatment MDSC levels in said sample is associated with shorter overall survival, tumor growth or progression-free survival.

6. The method according to claim 5, wherein said MDSC phenotype is selected from MDSC2, 3, 4, 5, and 6.

7. The method according to any of claims 1 to 6, wherein said MDSC phenotype is selected from MDSC1 and/or 2 in an RCC or CRC patient; selected from MDSC3 in a stage III-IV RCC patients, selected from MDSC4 in a stage IV melanoma patient; selected from MDSC1 to MDSC5, and preferably MDSC5 in a metastatic RCC patient; and selected from MDSC5 in a metastatic adenocarcinoma patient.

8. The method according to any of claims 1 to 7, wherein said biological sample is selected from a sample containing peripheral blood mononuclear cells (PBMC), such as, for example, whole blood, peripheral blood, or fractions thereof, buffy coat, tumor tissue, and bone marrow.

9. A method for detecting the effect of a cancer treatment in a patient, comprising determining the level of at least one myeloid-derived suppressor cell (MDSC) phenotype according to a method according to any of claims 1 to 8 in a biological sample obtained from a patient being treated for cancer, wherein a decrease of the level of said MDSC phenotype(s) as determined compared to a non-treated patient sample is indicative for an effective treatment of said cancer in said patient.

10. The method according to claim 9, wherein said patient is treated or has been pre-treated with an anti-cancer agent selected from cytokines, sorafenib, sunitinib, cyclophosphamide, and tyrosine kinase inhibitors (TKI).

11. The method according to claim 10, further comprising a prognosis of the effect of a cancer treatment in a patient, wherein said patient is treated or has been pre-treated with cyclophosphamide, and wherein a decrease of levels of the MDSC5 phenotype compared to a non-treated or pretreated patient sample is indicative for an effective treatment of said cancer in said patient.

12. The method according to any of claims 9 to 11, further comprising a monitoring of the effect of said cancer treatment in said patient, comprising repeating said determining step at least once.

13. The method according to any of claims 9 to 12, wherein said cancer treatment is selected from chemotherapy and/or immunotherapy, preferably comprising the use of an anti-cancer vaccine, optionally together with GM-CSF.

14. The method according to claim 13, wherein said anti-cancer vaccine is selected from an anti-cancer vaccine comprising a mixture of immunogenic peptides having a sequence selected from SEQ ID No. 1 to 10; SEQ ID No. 11 to 19 and 1, 5, 8, and 9; SEQ ID No. 20 to 29, and SEQ ID No. 30 to 37.

15. A diagnostic kit, comprising materials for performing a method according to any of claims 1 to 14 in one or separate containers, comprising at least one antibody specific for CD15; IL4Ra; CD14; CD11b; HLA-DR; CD33; Lin, and CD45; and optionally CD18; CD80; CD83; CD86; and HLA-I, optionally together with instructions for performing said method.

16. The diagnostic kit according to claim 15, wherein the antibody is labeled with a cytometry marker selected from Q605, V450, AF700, APC-H7, Cy7, and FITC.

17. The diagnostic kit according to claim 15 or 16, comprising at least one antibody selected from CD45 Q605, CD15 V450, CD124 PE, CD11b AF700, CD14 APC-H7, CD33 PE-Cy7, CD3 FITC, CD19 FITC, CD56 FITC, and CD14 FITC.

18. A method for inducing an immune response in a cancer patient, comprising
a) administering an anti-cancer vaccine to said cancer patient
b) performing a method according to any of claims 1 to 8 in a biological sample obtained from said patient being treated for cancer, wherein a decrease of the level of said MDSC phenotype(s) as determined compared to a patient sample before the treatment is indicative for the induction of an immune response in a cancer patient, and
c) optionally, repeating step a) based on the results as obtained in step b).

19. An improved method for treating cancer in a cancer patient in need thereof, comprising administering a suitable anti-cancer treatment to said cancer patient which decreases the level of at least one of said MDSC phenotype(s) as determined through a method according to any of claims 1 to 8 in a biological sample obtained from said patient being treated for cancer, compared to a patient sample before said treatment.

20. An improved method for treating cancer in a cancer patient in need thereof, comprising
a) administering an anti-cancer vaccine to said cancer patient,
b) performing a method according to any of claims 1 to 8 in a biological sample obtained from said patient being treated for cancer, wherein a decrease of the level of said MDSC phenotype(s) as determined compared to a patient sample before the treatment is indicative for a treatment of said cancer in said cancer patient, and
c) optionally, repeating step a) based on the results as obtained in step b).

21. The method according to any of claims 18 to 20, further comprising a monitoring of the immune response and/or treatment in said cancer patient, comprising repeating step b), and optionally step c) at least once.

22. The method according to any of claims 18 to 21, wherein said patient is furthermore treated or has been pre-treated with an anti-cancer agent selected from chemotherapy with an anti-cancer agent, cytokines, sorafenib, sunitinib, cyclophosphamide, and tyrosine kinase inhibitors (TKI).

23. The method according to any of claims 18 to 22, wherein said cancer is selected from renal cell carcinoma (RCC), colorectal cancer (CRC), gastric cancer (GC), melanoma, and adenocarcinoma.

Claims

1. A method for diagnosing and/or prognosing cancer, comprising

determining the level of at least one myeloid-derived suppressor cell (MDSC) phenotype in an MDSC population in a biological sample obtained from a patient based on at least one MDSC phenotype marker,

wherein said marker is selected from the group consisting of CD15; IL4Ra; CD14; CD11b; HLA-DR; CD33; Lin; and, optionally CD45; CD18; CD80; CD83; CD86; HLA-I; Live/Dead discriminator from a diagnostic kit, comprising these markers in one or separate containers, optionally together with instructions for performing said method,

wherein the antibody is labeled with a cytometry marker selected from Q605, V450, AF700, APC-H7, Cy7, and FITC and

wherein an increase of the level of said MDSC phenotypes compared to a non-cancer patient sample is indicative for cancer and/or a prognostic indicator for a treatment of said cancer.