Claims

1. A method for

a) diagnosing congestion or assessing or monitoring the extent of congestion or,

b) predicting or determining or monitoring need of therapy or intervention of congestion or predicting or determining or monitoring the success of a therapy or intervention of congestion or guiding a therapy or intervention of congestion or,

c) predicting decongestion or residual congestion after therapy or intervention of congestion or,

d) assessing decongestion or residual congestion after therapy or intervention of congestion or,

e) assessing the decision on hospital discharge,

in a subject having acute heart failure that is either new-onset AHF or acute decompensated HF or acute decompensated chronic HF or in a subject having chronic heart failure with worsening signs/symptoms of chronic heart failure,

wherein Pro-Adrenomedullin or fragments thereof of at least 5 amino acids is used as an early surrogate marker for congestion and

wherein said Pro-Adrenomedullin or fragment is selected from the group comprising Pro-Adrenomedullin according to SEQ ID No. 1 or PAMP according to SEQ ID No.: 2 or MR-proADM according to SEQ ID No.: 3 or mature ADM-NH2 according to SEQ ID No.: 4 or ADM-Gly according to SEQ ID No.: 5 or CT-proADM according to SEQ ID No.: 6.

2. A method of claim 1 comprising the steps:

- determining the level of Pro-Adrenomedullin or fragments thereof of at least 5 amino acids in a bodily fluid obtained from said subject; and

a) correlating said level of Pro-Adrenomedullin or fragments thereof with the extent of congestion in said subject or diagnosing congestion, wherein an elevated level above a certain threshold is indicative of congestion or the extent of congestion or,

b) correlating said level of Pro-Adrenomedullin or fragments thereof with success of a therapy or intervention of congestion in said subject, wherein a level below a certain threshold is predictive for a success of therapy or intervention of congestion, and wherein a level above a certain threshold is indicative for need of therapy or intervention of congestion or,

c) correlating said level of Pro-Adrenomedullin or fragments thereof with a prediction of decongestion or residual congestion after therapy or intervention of congestion, wherein an elevated level above a certain threshold predicts residual congestion after therapy or intervention of congestion whereas a level below a certain threshold predicts decongestion after therapy or intervention of congestion, or

d) correlating said level of Pro-Adrenomedullin or fragments thereof with decongestion or residual congestion after therapy or intervention of congestion, wherein an elevated level above a certain threshold indicates residual congestion after therapy or intervention of congestion whereas a level below a certain threshold indicates decongestion after therapy or intervention of congestion, or

e) correlating said level of Pro-Adrenomedullin or fragments thereof with the assessment of the decision on hospital discharge, wherein an elevated level above a certain threshold means that the subject shall not be discharged and wherein a level below a certain threshold means that the subject may be discharged,

wherein said Pro-Adrenomedullin or fragment is selected from the group comprising Pro-Adrenomedullin according to SEQ ID No. 1 or PAMP according to SEQ ID No.: 2 or MR-proADM according to SEQ ID No.: 3 or mature ADM-NH_2 according to SEQ ID No.: 4 or ADM-Gly according to SEQ ID No.: 5 or CT-proADM according to SEQ ID No.: 6.

3. A method according to claim 1 comprising the steps:

- determining the level of immunoreactive analyte by using at least one binder that binds to a region within the amino acid sequence of Pro-Adrenomedullin or fragments thereof of at least 5 amino acids in a bodily fluid obtained from said subject; and

a) correlating said level of immunoreactive analyte with the extent of congestion in said subject or diagnosing congestion, wherein an elevated level above a certain threshold is indicative of congestion or the extent of congestion or,

b) correlating said level of immunoreactive analyte with success of a therapy or intervention of congestion in said subject, wherein a level below a certain threshold is predictive for a success of therapy or intervention of congestion, and wherein a level above a certain threshold is indicative for need of therapy or intervention of congestion or

c) correlating said level of immunoreactive analyte with a prediction of decongestion or residual congestion after therapy or intervention of congestion, wherein an elevated level above a certain threshold predicts residual congestion after therapy or intervention of congestion whereas a level below a certain threshold predicts decongestion after therapy or

d) correlating said level of immunoreactive analyte with decongestion or residual congestion after therapy or intervention of congestion, wherein an elevated level above a certain threshold indicates residual congestion after therapy or intervention of congestion whereas a level below a certain threshold indicates decongestion after therapy or intervention of congestion, or

e) correlating said level of immunoreactive analyte with the assessment of the decision on hospital discharge wherein an elevated level above a certain threshold means that the subject shall not be discharged and wherein a level below a certain threshold means that the subject may be discharged,

wherein said Pro-Adrenomedullin or fragment is selected from the group comprising Pro-Adrenomedullin according to SEQ ID No. 1 or PAMP according to SEQ ID No.: 2 or MR-proADM according to SEQ ID No.: 3 or mature ADM-NH_2 according to SEQ ID No.: 4 or ADM-Gly according to SEQ ID No.: 5 or CT-proADM according to SEQ ID No.: 6.

4. A method according to any of claims 1 to 3, wherein said extent of congestion is expressed as congestion score, in particular a clinical congestion score.

5. A method of any of claims 1 to 4, wherein said subject is stratified

a) into groups of grades of congestion or,

b) into non-responder and/or responder, and/or bad responder to therapy or intervention of congestion or,

c) into a group with decongestion or into a group of residual congestion after therapy or intervention of congestion.

6. A method according to any of claims 1 to 5 wherein said fragment may be selected from MR-proADM according to SEQ ID No.: 3 or mature ADM-NH_2 according to SEQ ID No.: 4.

7. A method according to any of claims 1 to 6, wherein the level of Pro-Adrenomedullin or fragments thereof of at least 5 amino acids is determined by using a binder to Pro-Adrenomedullin or fragments thereof of at least 5 amino acids.

8. A method according to claim 7, wherein the binder is selected from the group comprising an antibody, an antibody fragment or a non-Ig-Scaffold binding to Pro-Adrenomedullin or fragments thereof of at least 5 amino acids.

9. A method according to any of claims 1 to 8, wherein said threshold is within a threshold range that is a threshold range for plasma mature ADM-NH_2 according to SEQ ID No.: 4 between 50 and 100 pg/ml and for plasma MR-proADM between 0.5 and 1.5 nmol/L, and for plasma CT-proADM between 85 and 350 pmol/L.

10. A method according to any of claims 1 to 9, wherein said determination of Pro-Adrenomedullin or fragments thereof of at least 5 amino acids is performed more than once in one patient.

11. A method according to claim 2 or claim 3 or any claim dependent therefrom, wherein the bodily fluid is taken at admission to a hospital or discharge of hospital.

12. A method according to any of claims 1 to 11, wherein said monitoring is performed in order to evaluate the response of said subject to preventive and/or therapeutic measures taken.

13. A method according to any of claims 1 to 12 in order to stratify said subjects into congestion grade groups.

14. A method according to any of claims 1 to 13 wherein said level of Pro-Adrenomedullin or fragments thereof or said level of immunoreactive analyte is correlated with a risk of death or an adverse event in subject having acute heart failure, wherein an elevated level above a certain threshold is predictive for an enhanced risk of death or adverse events.

15. A method according to any of claims 1 to 14 wherein said level of Pro-Adrenomedullin or fragments thereof or said level of immunoreactive analyte is used for guidance of therapy or intervention of congestion, wherein therapy or intervention is indicated if said level of Pro-Adrenomedullin or fragments is above a certain threshold and wherein-, therapy or intervention of congestion is not indicated if said level of Pro-Adrenomedullin or fragments is below a certain threshold.

16. A method according to any of claims 1 to 15 wherein said level of Pro-Adrenomedullin or fragments thereof or said level of immunoreactive analyte is used for determining the need of therapy or intervention of congestion.

17. A method according to any of claims 1 to 16 wherein said intervention or therapy is selected from the group comprising administration of diuretics, administration of inotropes, administration of vasodilators, ultrafiltration.