Brief Summary	Date of Change	Brief Summary	Action Done
	21/01/2025	This is a single centre, open label, case-control, longitudinal, cross sectional cohort study with single dose of Body Revival on breast cancer post surgery recovery patients in combination with / or without regular therapeutic regime to assess the effectiveness of Body Revival supplement to prolong PFS and improvement of QoL. Approximately 48 subjects at single site with radiotherapy and chemotherapy treated post-operative breast cancer of greater than 1 and no more than 6 months from their surgery and chemotherapy/radiotherapy will be randomized. Allocation will be stratified by 1:1 treatment vs. case control of selected four arms.Control groups will not receive Body Revival$^{Â®}$ but will be allowed their regular conventional therapy, if any. Control groups will also be eligible to attend scheduled follow-ups. **The groups or arms will be as follows:** Arm I Radiotherapy (RT) + Body Revival Arm II RT + Control Arm III Chemotherapy (CT) + Body Revival Arm IV CT + Control Additionally, Arm I and Arm III will receive test medicine for 12 weeks, while Arm II and Arm IV without test medicine. **Selection Criteria** Each subject must meet the following criteria to be enrolled in this study Female subjects â‰¥ 18 years A histologically or cytologically confirmed diagnosis of breast cancer (stage IIâ€“IV) Or must have history of measurable disease by CT or MRI scan Have been treated with surgery / first line chemotherapy / radiotherapy of not more than six months Must have no report of relapsed Life expectancy of â‰¥12 months as estimated by the Investigators Other significant medical conditions must be well-controlled and stable in the opinion of the Investigators for at least 30 days prior to Study Day 1 Subjects must provide written informed consent and be able to comply with the protocol procedures All subjects will be examined and monitored for consecutive 12 weeks. Follow-up schedule visit period will be: 1st Follow-up: 4 wks after randomization (Â± 5days) 2nd Follow-up: 4 wks after 1st Follow-up (Â± 5days) 3rd Follow-up: 4 wks after 2nd Follow-up (Â± 5days) **Efficacy & Safety Assessments** Physical examinations (including vital signs) Subject reported on Quality of Life (QoL) Karnofsky Performances Progression free survival (PFS) based on serologic CA-15.3 response Complete blood haemogram Clinical laboratory tests (serum chemistry) Radiological assessments (CT-Scan) Adverse events (AEs) **Statistical Procedure** For the primary efficacy analyses, multiplicity for the comparison of Body Revival vs. control group will adjusted so that the study level type I error rate controlled to be lower than 0.05 significance level. Specific testing procedures which maintain the study level type I error rate at a lower level for this purpose are specified in statistical analysis plan.Intent-to-Treat Population (ITT), defined as all randomized subjects. This is the primary analysis population for all efficacy endpoints. Safety Analysis Set (SAS), defined as all randomized subjects who will received at least one dose of study drug and who has at least one safety assessment following the first follow up, analyzed by the treatment received. Evaluable population defined as all randomized subjects who have baseline and at least one on-treatment assessment performed. Categorical data between the baseline and post treatment will be compared with the Ï‡2 test, and continuous data will be analyzed by ANOVA and post-hoc analysis where applicable. Alpha for statistical significance will be set at $p<0.05$.	Record Modification
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	Approximately 48 subjects at single site with radiotherapy and chemotherapy treated post-operative breast cancer of greater than 1 and no more than 6 months from their surgery and chemotherapy/radiotherapy will be randomized. Allocation will be stratified by 1:1 treatment vs. case control of selected four arms.Control groups will not receive Body RevivalÂ® but will be allowed their regular conventional therapy, if any. Control groups will also be eligible to attend scheduled follow-ups. **The groups or arms will be as follows:** Arm I Radiotherapy (RT) + Body Revival Arm II RT + Control Arm III Chemotherapy (CT) + Body Revival Arm IV CT + Control Additionally, Arm I and Arm III will receive test medicine for 12 weeks, while Arm II and Arm IV without test medicine. **Selection Criteria** Each subject must meet the following criteria to be enrolled in this study Female subjects â‰¥ 18 years A histologically or cytologically confirmed diagnosis of breast cancer (stage IIâ€“IV) Or must have history of measurable disease by CT or MRI scan Have been treated with surgery / first line chemotherapy / radiotherapy of not more than six months Must have no report of relapsed Life expectancy of â‰¥12 months as estimated by the Investigators Other significant medical conditions must be well-controlled and stable in the opinion of the Investigators for at least 30 days prior to Study Day 1 Subjects must provide written informed consent and be able to comply with the protocol procedures All subjects will be examined and monitored for consecutive 12 weeks. Follow-up schedule visit period will be: 1st Follow-up: 4 wks after randomization (Â± 5days) 2nd Follow-up: 4 wks after 1st Follow-up (Â± 5days) 3rd Follow-up: 4 wks after 2nd Follow-up (Â± 5days) **Efficacy & Safety Assessments** Physical examinations (including vital signs) Subject reported on Quality of Life (QoL) Karnofsky Performances Progression free survival (PFS) based on serologic CA-15.3 response Complete blood haemogram Clinical laboratory tests (serum chemistry) Radiological assessments (CT-Scan) Adverse events (AEs) **Statistical Procedure** For the primary efficacy analyses, multiplicity for the comparison of Body Revival vs. control group will adjusted so that the study level type I error rate controlled to be lower than 0.05 significance level. Specific testing procedures which maintain the study level type I error rate at a lower level for this purpose are specified in statistical analysis plan.Intent-to-Treat Population (ITT), defined as all randomized subjects. This is the primary analysis population for all efficacy endpoints. Safety Analysis Set (SAS), defined as all randomized subjects who will received at least one dose of study drug and who has at least one safety assessment following the first follow up, analyzed by the treatment received. Evaluable population defined as all randomized subjects who have baseline and at least one on-treatment assessment performed. Categorical data between the baseline and post treatment will be compared with the Ï‡2 test, and continuous data will be analyzed by ANOVA and post-hoc analysis where applicable. Alpha for statistical significance will be set at $p<0.05$.	
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Or must have history of measurable disease by CT or MRI scan

Have been treated with surgery / first line chemotherapy / radiotherapy of not more than six months

Must have no report of relapsed

Life expectancy of â‰¥12 months as estimated by the Investigators

Other significant medical conditions must be well-controlled and stable in the opinion of the Investigators for at least 30 days prior to Study Day 1

Subjects must provide written informed consent and be able to comply with the protocol procedures

All subjects will be examined and monitored for consecutive 12 weeks. Follow-up schedule visit period will be:

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Efficacy & Safety Assessments

Physical examinations (including vital signs)

Subject reported on Quality of Life (QoL)

Karnofsky Performances

Progression free survival (PFS) based on serologic CA-15.3 response

Complete blood haemogram

Clinical laboratory tests (serum chemistry)

Radiological assessments (CT-Scan)

Adverse events (AEs)

Statistical Procedure

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