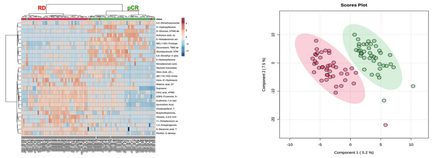
A-2234 Preliminary Results from the NEOMET Trial: Nutritional and Exercise Interventions During Neoadjuvant Chemotherapy in Early Breast Cancer

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Introduction

Host metabolic status and **body composition** are emerging determinants of treatment response and prognosis in early breast cancer (eBC).

The **SeNEOAD** study identified a metabolomic signature associated with pathological complete response (pCR) after neoadjuvant therapy (NAT). Among 445 small molecules analyzed, 61 were differentially expressed in patients with pCR versus residual disease (RD) ($p<0.05$); patients with RD showed lower levels of fatty acids, such as 9-hexadecenoic acid ($p <0.001$), doconexent ($p<0.001$).



The aim of the **NEOMET** trial is to to evaluate whether lifestyle interventions, including dietary supplementation and physical exercise, can modify plasma metabolomic signatures in early breast cancer patients undergoing neoadjuvant therapy (NAT).

Study design

Inclusion criteria

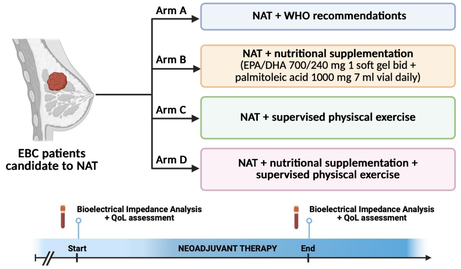
- Stage I-III - Candidate to NAT
- Ability to fill a nutritional daily diary
- Compliane to study procedures
- Written informed

Statistical Considerations

- A total of 160 pts will be enrolled and randomised
- Estimated accrual period: 20 months.

Biological analyses

- Metabolomics analysis is performed at baseline (T0) and after NAT (T1), before surgery, by mass spectrometry
- Gene-expression profiling of metabolic pathway will be assessed, using the nCounter Metabolic Pathways available panel and RNA-seq on Illumina platform.



Results

Overall, 31 patients have been enrolled in the NEOMET trial to date and 26 have completed NAT

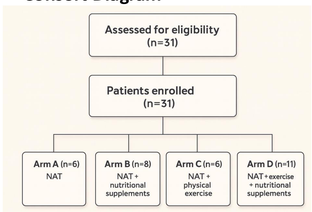
Treatments and Schedules

Triple negative:
1) Weekly CBDCA AUC 1.5 + paclitaxel 80 mg/mq for 12 weeks →
2) EC 90/600 g1q21 for 4 cycles (+ pembrolizumab 200 mg)
2) Weekly CBDCA AUC 2 + paclitaxel 80 mg/mq → 4 EC 90/600 g1q14 for 4 cycles

HER2 positive:
1) 18 weekly paclitaxel 80 mg/mq + CBDCA AUC 1.5 (+ trastuzumab/pertuzumab q21)
2) 12 weekly paclitaxel 80 mg/mq + CBDCA AUC 1.5 (+ trastuzumab + pertuzumab q21) → 4 EC90/600 q21
3) 4 EC 90/600 q21 → 12 weekly paclitaxel 80 mg/mq (+ trastuzumab q21)

ER positive:
1) 4 cycles of EC 90/600 g1q14 → 12 weekly paclitaxel 80 mg/mq
2) 4 cycles of EC 90/600 g1q21 → 12 weekly paclitaxel 80 mg/mq

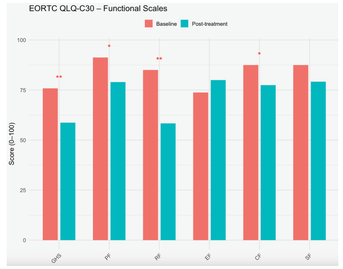
Consort Diagram

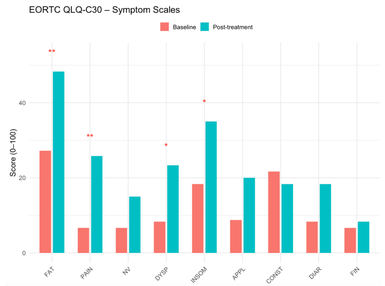


Patient Characteristscs

	Arm A (n=6, 19.4%)	Arm B (n=8, 25.8%)	Arm C (n=6, 19.4%)	Arm D (n=11, 35.4%)	Total (n=31, 100%)
Median age - yr	53 (31-70)	54 (34-68)	52 (31-61)	52 (35-66)	52 (31-70)
ECOG 0	6 (100.0)	8 (100.0)	6 (100.0)	11 (100.0)	31 (100.0)
Menopausal status					
Premenopausal	2 (33.3)	4 (50.0)	3 (50.0)	7 (63.6)	16 (51.6)
Postmenopausal	4 (66.7)	4 (50.0)	3 (50.0)	4 (36.4)	15 (48.4)
Biological subtype					
Luminal	2 (33.3)	3 (37.5)	1 (16.7)	4 (36.4)	10 (32.3)
HER2+	4 (66.7)	3 (37.5)	0 (0)	6 (54.5)	13 (41.9)
TNBC	0 (0)	2 (25.0)	5 (83.3)	1 (9.1)	8 (25.8)
Clinical stage					
II	5 (83.3)	8 (100.0)	4 (66.7)	8 (72.7)	25 (80.6)
III	1 (16.7)	0 (0)	2 (33.3)	3 (27.3)	6 19.4)
Nodal involvement					
Negative	3 (50.0)	4 (50.0)	4 (66.7)	8 (72.7)	19 (61.3)
Positive	3 (50.0)	4 (50.0)	2 (33.3)	3 (27.3)	12 (38.7)
pCR					
Yes	4 (66.7)	3 (37.5)	1 (16.7)	1 (9.1)	9 (29.0)
No	2 (33.3)	2 (25.0)	3 (50.0)	4 (36.4)	11 (35.5)
NA	0 (0)	3 (37.5)	2 (33.3)	6 (54.5)	11 (35.5)

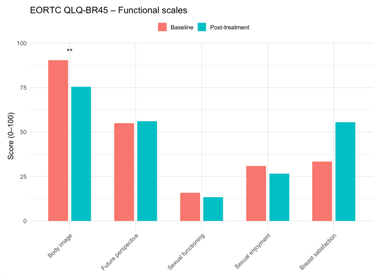
QoL Assessment

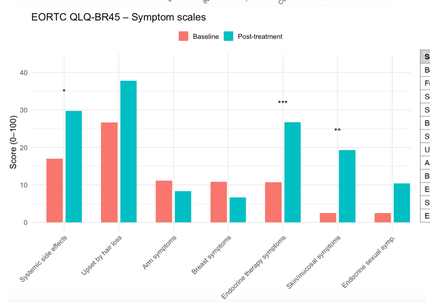




EORTC QLQ-C30 – Summary of Pre/Post Changes

Scale	Pre	Post	Delta	p-value	Interpretation
Global Health Status / Quality of Life	75.8	58.8	-17.1	0.009	QoL ↓ (significant)
Physical Functioning	91.3	79.0	-11.8	0.016	Physical functioning ↓ (significant)
Role Functioning	85.0	58.3	-26.7	0.004	Role functioning ↓ (significant)
Emotional Functioning	79.8	80.0	+6.3	0.146	Stable / slight improvement
Cognitive Functioning	87.5	77.5	-10.0	0.040	Cognitive functioning ↓ (significant)
Social Functioning	87.5	79.2	-8.3	0.081	Trend toward worsening
Fatigue	27.2	48.3	+21.1	0.004	Fatigue ↑ (significant)
Pain	6.7	25.8	+19.2	0.006	Pain ↑ (significant)
Nausea / Vomiting	6.7	15.0	+8.3	0.072	Trend toward worsening
Dyspnea	8.3	23.3	+15.0	0.033	Dyspnea ↑ (significant)
Insomnia	18.3	35.0	+16.7	0.012	Insomnia ↑ (significant)
Appetite Loss	8.8	20.0	+12.3	0.112	Not significant
Constipation	21.7	18.3	-3.3	0.710	Stable
Diarrhea	8.3	18.3	+10.0	0.170	Not significant
Financial Difficulties	6.7	8.3	+1.7	0.850	Stable





EORTC QLQ-BR45 – Summary of Pre/Post Changes

Scale	Pre	Post	Delta	p-value	Interpretation
Body Image (BI)	90.4	75.4	-15.4	0.0036	Body image ↓ (significant)
Future perspective (FU_BR)	55.0	56.1	0.0	1.0000	Stable
Sexual functioning (SX)	15.8	13.3	-1.8	0.5775	No meaningful change
Sexual enjoyment (SE)	31.0	26.7	-6.7	0.5862	No meaningful change
Breast satisfaction (BS)	33.3	55.6	0.0	NA	Not testable (many NA)
Systemic side effects (SYS)	17.0	29.8	+12.8	0.0244	Systemic side effects ↑ (significant)
Upset by hair loss (HU)	26.7	37.8	0.0	NA	Not testable (conditional item)
Arm symptoms (ARM)	11.1	8.3	-2.8	0.5898	Stable
Breast symptoms (BR_SYM)	10.8	6.7	-4.2	0.3033	Stable
Endocrine therapy symptoms (ET)	10.7	26.7	+16.0	0.0004	Endocrine symptoms ↑ (significant)
Skin/mucosal symptoms (SM)	2.5	19.3	+16.8	0.0023	Skin/mucosal symptoms ↑ (significant)
Endocrine sexual symptoms (ES)	2.5	10.4	+8.5	0.0553	Trend to worsening

Bioelectrical Impedance Analysis (BIA)

- **Fat-Free Mass (FFM):** includes all non-fat components of the body.
- **Skeletal Muscle Mass (SMM):** Represents 70% of total muscle mass. Correlates with physical function and overall health status.
- **Fat Mass (FM):** Composed mainly of glycerol and fatty acids, serving as an energy reserve.

BIA baseline versus end of treatment

Measure	N (paired)	Pre (kg)	Post (kg)	Delta	p-value	Interpretation
Fat-Free Mass (FFM)	21	44.8	46.4	+1.6	0.017	↑ FFM (significant)
Fat Mass (FM)	21	21.0	19.5	-1.5	0.55	↓ Fat mass (NS)
Skeletal Muscle Mass (SMM)	16	20.0	21.5	+1.5	0.033	↑ SMM (significant)

BIA by treatment Arm

Comparison	ΔFFM (kg)	ΔFM (kg)	ΔSMM (kg)	Interpretation
Arm A (n=4) vs B+C+D (n=17)	+1.25 vs +1.66	+1.25 vs –2.13	+0.95 vs +1.69	Others lose FM and gain more SMM
Arm A (n=4) vs B+D (n=13)	+1.25 vs +2.25	+1.25 vs –3.21	+0.95 vs +2.68	Stronger FM drop and SMM gain in B+D
Arm A (n=4) vs C+D (n=12)	+1.25 vs +1.48	+1.25 vs –2.82	+0.95 vs +2.01	Same direction: BCD e CD improve more

Conclusions

Preliminary findings from the ongoing NEOMET trial suggest that integrating nutritional and exercise interventions during NAT in eBC is feasible and may help preserve lean mass and enhance physical function. Additional analyses will clarify the impact on treatment tolerance and patient well-being.

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