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Using a mixed probiotic/prebiotic supplement (MBR-01) to help prevent diarrhea in patients taking abemaciclib for early breast cancer

Submission date 10/12/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 11/12/2025	**Overall study status** Completed	
Last Edited 11/12/2025	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

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Additional identifiers

Study information

Scientific Title
A mixed probiotic/prebiotic intervention (MBR-01) for the management of diarrhea during abemaciclib treatment of early breast cancer: a single-center prospective case–control pilot study

Study objectives
Primary objective:
To preliminarily assess whether MBR-01 reduces the incidence and severity of abemaciclib-induced diarrhea.

Secondary objectives:
1. To evaluate whether the intervention reduces the need for dose reductions, treatment interruptions, or discontinuations caused by gastrointestinal toxicity.
2. To assess changes in patient-reported stool frequency and consistency collected through daily electronic diaries.
3. To determine the impact of the intervention on health-related quality of life (HRQoL), using the EORTC QLQ-C30 and QLQ-BR23 questionnaires, with a specific focus on emotional, role, and physical functioning (QLQ-C30) as well as body image and sexual functioning (QLQ-BR23).
4. To explore the effects of the intervention on patient-reported outcomes through a custom QoL interference score and diary-based stool frequency measures.
5. To explore changes in gut microbiota composition and diversity from baseline to week 12, and to investigate their potential association with the occurrence and severity of diarrhea.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/10/2019, Comitato Etico ATS Val Padana (Viale Concordia 1, Cremona, 26100, Italy; +39 (0)372408430; comitato.etico@asst-cremona.it), ref: 34236 - 19

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Patients were assigned to the control or intervention group based on their willingness to receive prophylactic MBR-01, a standardized probiotic and prebiotic protocol

Purpose
Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Prevention or symptomatic reduction of abemaciclib-induced diarrhea in patients with early stage hormone receptor positive (HR+)/HER2-negative breast cancer candidate to receive abemaciclib in clinical practice

Interventions
Patients are assigned to the control or intervention group based on their willingness to receive prophylactic MBR-01, a standardized probiotic and prebiotic protocol.

Patients in the experimental arm receive the MBR-01 prebiotic/probiotic protocol 4 cp/8 h + abemaciclib 150 mg 1 cp/12 h + letrozole 2.5 mg 1 cp/24 h for 12 weeks.

Patients in the control group receive abemaciclib 150 mg 1 cp/12 h + letrozole 2.5 mg 1 cp/24 h for 12 weeks.

Intervention Type
Supplement

Primary outcome(s)
1. Incidence and severity of abemaciclib-induced diarrhea measured using National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) v5.0 grading (clinical assessment) at baseline and week 12

Key secondary outcome(s))
1. Need for dose reductions, treatment interruptions, or discontinuations due to diarrhea measured using medical record review and clinician-reported treatment modifications at continuously assessed throughout the 12-week treatment period

2. Patient-reported outcomes (PROMs): stool frequency measured using electronic diary counts (ePRO) at continuously assessed throughout the 12-week treatment period

3. Health-related quality of life (HRQoL): predefined functional domains measured using EORTC QLQ-C30: emotional, role, physical functioning; EORTC QLQ-BR23: body image, sexual functioning; analysis: non-parametric comparative tests (Mann–Whitney U, Wilcoxon signed rank) at baseline and week 12

4. Patient-reported outcomes (PROMs): exploratory quality of life interference measured using custom composite score derived from electronic diaries at baseline and week 12

5. Gut microbiota composition and diversity measured using alpha diversity: Shannon, Simpson, Chao1 indices compared via appropriate non-parametric tests; beta diversity: Bray–Curtis, weighted UniFrac, analyzed with PERMANOVA at baseline and week 12

6. Correlation between microbiota features and diarrhea outcomes measured using Spearman correlation using taxa with significant overall shifts at baseline and week 12

7. Predictors of grade ≥2 diarrhea measured using multivariable logistic regression including clinical and microbial baseline features at baseline

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Women aged ≥18 years
2. Histologically confirmed HR+/HER2– early breast cancer at high-risk of recurrence (≥4 positive axillary lymph nodes, or 1–3 positive nodes with additional features such as tumor size ≥5 cm, histologic grade 3, or Ki-67 ≥20%), candidate to receive abemaciclib
3. Patients were deemed unsuitable for adjuvant chemotherapy due to comorbidities frailty, or patient preference
4. Eastern Cooperative Oncology Group (ECOG) performance status 0–2
5. Adequate hematologic and organ function
6. Ability to provide fecal samples
7. Ability to provide informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
85 years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Prior exposure to CDK4/6i
2. Chronic diarrheal disorders
3. Inflammatory bowel disease
4. Intestinal resection affecting absorption

5. Systemic antibiotic, proton pump inhibitors or probiotic use within 4 weeks prior to enrollment
6. Immunosuppressive treatment
7. Concurrent participation in another interventional study

Date of first enrolment
02/01/2023

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
Italy

Study participating centre
ASST of Cremona
Viale Concordia 1
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Sponsor information

Organisation
Azienda Socio Sanitaria Territoriale di Cremona

ROR
https://ror.org/02h6t3w06

Funder(s)

Funder type

Funder Name
Mednote S.r.l.

Funder Name
Copan Italia S.p.a.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available