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How are clinical trials for breast cancer treatments currently being designed? A clinical trial database analysis

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BACKGROUND & OBJECTIVE

- **Breast cancer** is highly prevalent among women, with an impact on **patients' quality of life**
- New treatments developed and tested in clinical trials

- *Provide a **comprehensive overview** of **breast cancer clinical trials***
  - *How are the clinical trials **designed**?*
  - *What are the **endpoints** in the clinical trials?*
  - *Whether **patients are involved** in clinical trials*
  - *If and how **patients' needs and QoL** are assessed*

METHODS - *Database analysis*

- **Database:** ClinicalTrials.gov
- Search conducted **November 2024**

Applied filters in ClinicalTrials.gov
(i) female
(ii) adult participants (18-64 years old)
(iii) completed trials
(iv) trials with results
(v) phase III and phase IV
(vi) interventional studies

Important note: All filters represent minimum inclusion requirements; broader study characteristics (e.g., wider age ranges or both sexes) were allowed.

- Systematically **screening** of the trials after applying the filters
- **Data extraction** in a predefined excel table
- *Patient involvement was assessed by evaluating secondary endpoints in the clinical trials*

RESULTS - *preliminary findings*

- **280 trials** were **identified** and **analysed**
- Included trials started between 1997-2021

Clinical trials (N=280)	
Clinical phase	
Phase III	244 (87%)
Phase IV	36 (13%)
Primary purpose of clinical trial	
Treatment	216 (77%)
Supportive care	32 (11%)
Prevention	14 (5%)
Diagnostic	11 (4%)
Other/Not specified	7 (3%)
Most mentioned treatment categories in the clinical trials (also in combinations)	
Chemotherapy	114
Targeted therapy	117
Hormonal therapy	64

➢ **Number of participants in the trial**
- Median: 433,5
- 9 (min) – 9779 (max)

➢ **Follow up time**
- Median: 39 months
- 6 hours (min) – 190 months (max)

➢ **Breast cancer subtype included in trial** – not specified in 151 trials

(co-)primary endpoints most identified

1. Progression free survival (64 trials)
2. Disease free survival (41 trials)
3. Overall survival (23 trials)
4. Pathologic complete response (16 trials)

Patient involvement

➢ Assessment of patients' needs and QoL via questionnaires (103 trials)

➢ *Non-breast cancer specific questionnaires*
- Cancer specific: EORTC QLQ-C30
- Non-disease specific: EQ-5D
- Non-disease specific: VAS

➢ *Breast cancer specific questionnaires*
- FACT-B
- EORTC-QLQ-BR23

CONCLUSIONS - *preliminary findings*

- Unclear elements in trial design (i.e., subtypes of breast cancer patients included)
- Strongly focussed on survival-based endpoints
- Limited information whether patients are involved and whether needs are evaluated

LIST OF ABREVIATIONS

EORTC QLQ: European Organization for Research and Treatment for Cancer Quality of Life Questionnaire; EQ-5D: EuroQol 5D; FACT-B: Functional Assessment of Cancer Therapy – Breast; QoL: Quality of Life; VAS: Visual Analogue Scale

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