COMET Study (AFT-25)

Comparing an Operation to Monitoring, with or without Endocrine Therapy for low-risk DCIS

Lynch T, Frank L, Basila D, Pinto D, Collyar D, Partridge A, Thompson A, Davies L, Donovan J, Hwang S.

TAP TO RETURN TO KIOSK MENU

rationale/ objective
study schema
treatment plan/ intervention
key eligibility criteria
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follow up

RATIONALE

- Approximately 50,000 women in the U.S. are diagnosed with ductal carcinoma *in situ* (DCIS) each year
- Without treatment, approximately 20-30% will experience a future invasive breast cancer (1)
- However, over 97% of women are currently treated with surgery +/- radiation (2)
- An alternative to surgery for low-risk DCIS is active monitoring (AM): a management approach in which mammograms/physical exams are used to monitor breast changes and determine when, or *if*, surgery is needed
- The **COMET** study compares the risks and benefits of AM and surgery in the setting of a phase III pragmatic randomized clinical trial

OBJECTIVE

- Primary objective: assess whether the 2-, 5-, and 7-year ipsilateral invasive breast cancer rate for AM is non-inferior to that for surgery
- Patient reported outcomes (PROs) will enable comparison of health-related quality of life and psychosocial outcomes between surgery and AM groups at baseline, 6-months and years 1-5

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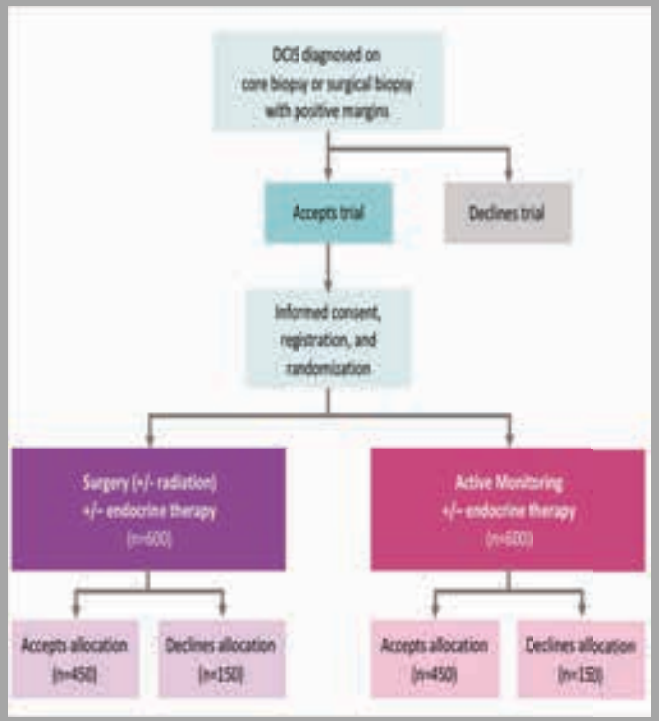
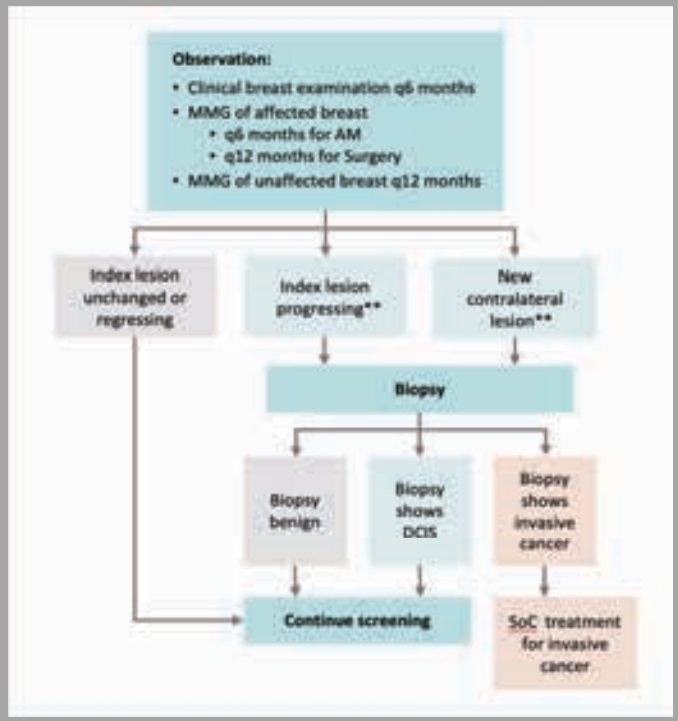
COMET Study Flow Diagram



COMET Surveillance Protocol



STUDY SCHEMA

ALLIANCE FOUNDATION TRIALS, LLC

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Clinical Outcomes	PRO: QOL and Psychosocial Outcomes
Primary endpoint: • Ipsilateral invasive breast cancer rate in Surgery and AM arms at median f/up of 2-years	
Secondary endpoints: • 2-year mastectomy/breast conservation rate • 2-year contralateral invasive breast cancer rate • 2-year overall/disease-specific survival	**Secondary endpoints:** • Health-related QOL (baseline, 6 months, years 1-5) • Anxiety and depression (baseline, 6 months, years 1-5) • Intolerance of uncertainty (baseline, 2-years) • Coping (baseline)
Other endpoints: • 2-year breast MRI rate • 2-year breast biopsy rate • 2-year radiation rate • 2-year chemotherapy rate	**Exploratory endpoints:** • Symptoms, pain (baseline, 6 months, years 1-5) • Body image, sexual function (baseline, 6 months, years 1-5) • Adherence to hormonal therapy (6 months, years 1-5) • Quality of decision-making (baseline, 2-years) • Knowledge and risk perception (baseline, 2-years) • Financial burden (6 months)

TREATMENT PLAN / INTERVENTION

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Inclusion criteria

- Age >40 at diagnosis
- All grade I and II DCIS (irrespective of necrosis/comedonecrosis)
- ADH/borderline DCIS
- Pathologic confirmation of grade I/II DCIS without invasion by 2 local pathologists
- ER and/or PR ≥ 10%; HER2-negative (0, 1+, or 2+ if testing performed)
- No evidence of breast mass on physical examination/breast imaging within 6 months of registration

KEY ELIGIBILITY CRITERIA

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- Planned accrual goal 1,200 randomized patients across 100 Alliance for Clinical Trials in Oncology sites
- Projected rate of 25% will withdraw or decline allocation (will continue to complete PRO surveys)
- Approximately 900 patients treated according to randomized arm, analyzed in an intent-to-treat analysis
- 2-year invasive cancer rate in Surgery group assumed to be 0.10 with a non-inferiority margin of 0.05
- Sample size of n=446 per group will have 80% power to detect the specified non-inferiority margin

STATISTICAL PLAN

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- COMET study accrual:
  - **80+ sites** activated
  - **400 patients** enrolled
- COMET Patient Leadership Team (PLT):
  - Ongoing review/revision of all COMET study materials
  - 1-1 calls with sites to discuss recruitment issues
- COMET Recruitment Enhancement Strategy (CRESt) (Louise Davies/Jenny Donovan):
  - Based on Quintet Recruitment Intervention (QRI)
  - COMET Core Narrative developed
- Translational Working Group (Alastair Thompson):
  - **300+ blood/tissue samples** collected
  - **Breast images collected for 300+** patients
- PRO Survey Working Group (Ann Partridge):
  - Baseline survey completion rate (99%)
  - 6M survey completion rate (84%)

PROGRESS TO DATE

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FUNDING SUPPORT

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2. *Worni M, Greenup R, Akushevich I, et al. Trends in treatment patterns and outcomes for DCIS: a SEER population-based analysis. Journal of Clinical Oncology 2014 ASCO Meeting Abstracts*

To learn more about the COMET Study, please contact Thomas Lynch (Project Manager): thomas.lynch2@duke.edu. All statements in this poster are solely those of the authors and do not necessarily represent the views of PCORI, its Board of Governors or Methodology Committee.