ALLIANCE FOUNDATION TRIALS, LLC

COMET Study (AFT-25)
Comparison of Operative to Monitoring and Endocrine Therapy for Low-risk DCIS

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

COMET
A Study for Low Risk DCIS
Expanding Knowledge and Options

pcori

TAP TO RETURN TO KIOSK MENU

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

- Approximately 50,000 women in the U.S. are diagnosed with ductal carcinoma *in situ* (DCIS) each year
- Without treatment, approximately 20-30% of DCIS will lead to invasive breast cancer (1)
- However, over 97% of women are currently treated with guideline-concordant care (GCC) including surgery and/or radiation (2)
- An alternative to GCC for low-risk DCIS is active surveillance (AS) which focuses on early detection of invasion should it occur, rather than “treatment” of DCIS
- The **COMET** study will compare risks and benefits of AS versus GCC in the setting of a Phase III pragmatic

RATIONALE

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

OBJECTIVE

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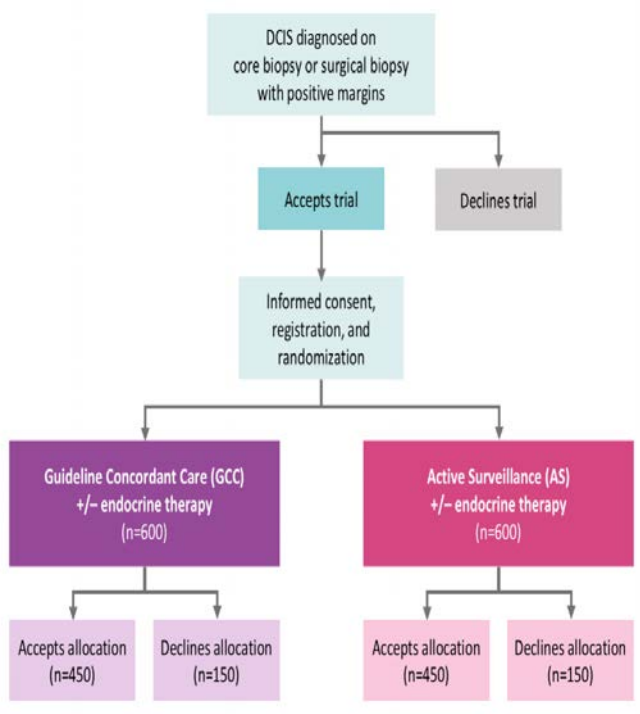
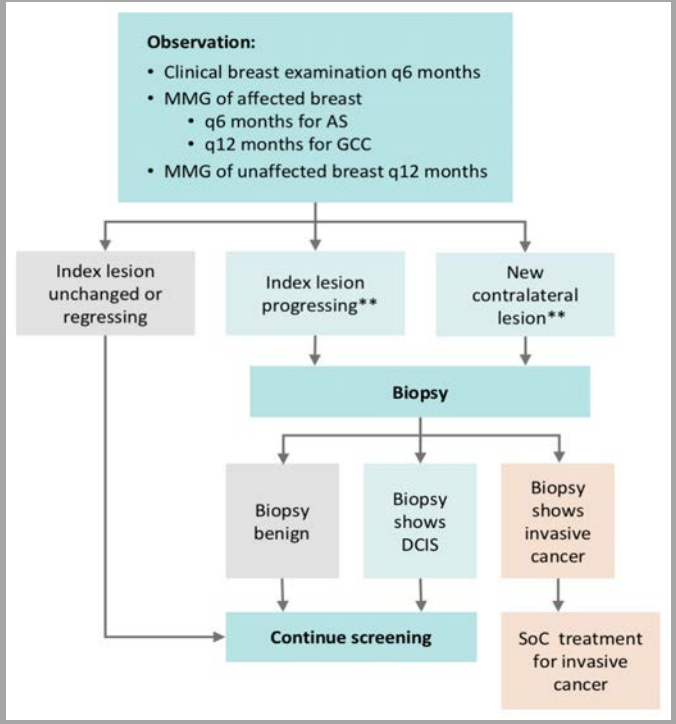
COMET Study Flow Diagram



COMET Surveillance Protocol



STUDY SCHEMA

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Clinical Outcomes	PRO: QOL and Psychosocial Outcomes
Primary endpoint: 2-year ipsilateral invasive cancer rate	
Secondary endpoints: • 2-year mastectomy/breast conservation rate • 2-year contralateral invasive cancer rate • 2-year overall/disease-specific survival	**Secondary endpoints: (baseline, 6 months, years 1-5)** • Health-related QOL • Anxiety and depression
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) • Quality of decision-making (baseline, 2-years) • Knowledge and risk perception (baseline, 2-years) • Financial burden (6 months)

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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 disease on physical examination/breast imaging within 6 months of registration

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- Planned accrual goal 1200 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 GCC 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 opened (July 2016)
- First site activated (February 2017)
- 75+ sites activated to date
- 100+ patients enrolled to date
- Comparable studies taking place in UK (LORIS) and Europe (LORD)
- Planned combined analysis of data
- Clinicaltrials.gov: NCT02926911

PROGRESS TO DATE

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FUNDING SUPPORT

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CONTACT US / REFERENCES

1. *Ozanne EM, Shieh Y, Barnes J, et al. Characterizing the impact of 25 years of breast cancer treatment. Breast Cancer Res Treatment, 129: 165-73. 2011*
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.