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*DOUBLE BLIND RANDOMISED CONTROLLED TRIAL EVALUATING EFFICACY OF CENTCHROMAN IN FIBROADENOMA AS COMPARE TO PLACEBO(*The FIBROCENT STUDY)

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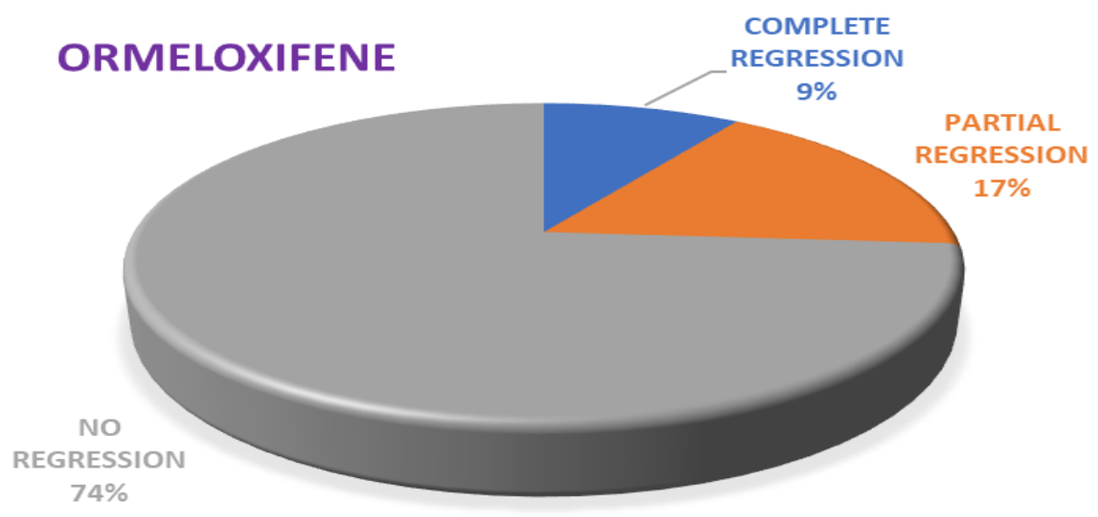
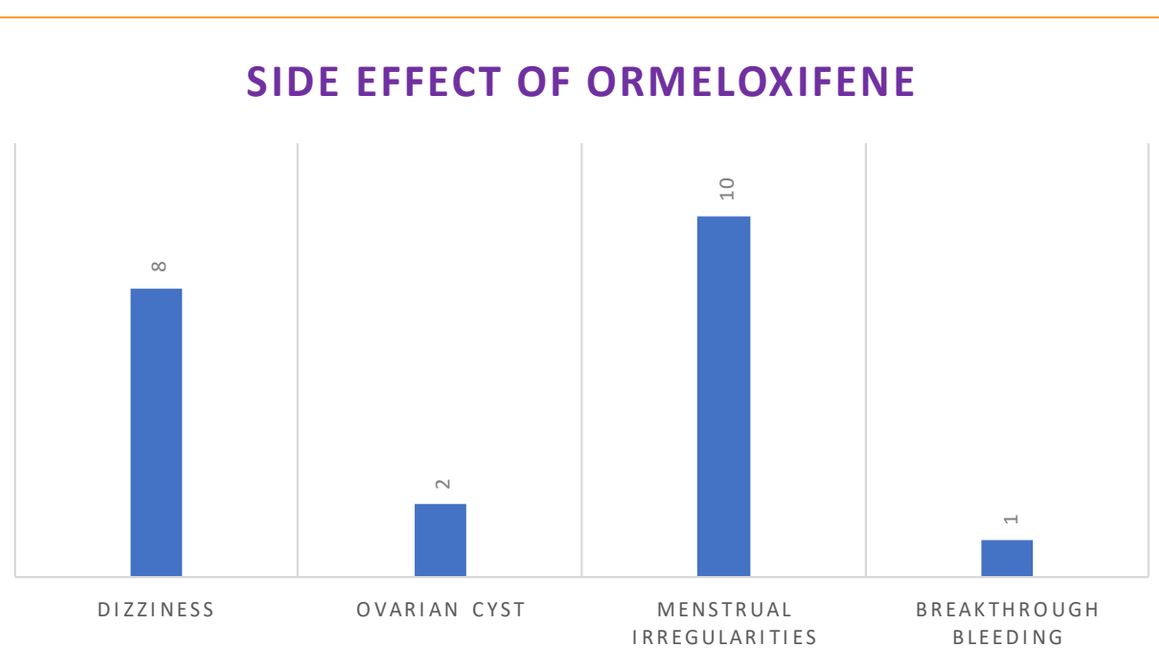
Introduction: Fibroadenoma is a prevalent benign breast condition affecting young women. Treatment options have evolved, with surgery being replaced by observation and pharmacological treatments. **Ormeloxifene, a non-steroidal selective estrogen receptor modulator**, has been proposed for fibroadenoma regression.

Objective:
To evaluate the effectiveness of Ormeloxifene (Centchroman) in the regression of fibroadenoma in a double blind, randomized controlled trial.

Methods:
Study Design: Double-blind, placebo-controlled, randomized trial.
Duration: August 2022 - October 2023.
Participants: 130 patients with biopsy-proven fibroadenoma.
Groups: 65 patients in the Ormeloxifene group, 65 in the placebo group.
Intervention:
Ormeloxifene (30 mg) every other day for 3 months.
Placebo every other day for 3 months.
Outcome Measures:
Primary: Regression of fibroadenoma (complete or partial) assessed by ultrasonography (USG)
Secondary: Adverse events related to treatment.
Follow up via ultrasonography of breast and pelvis at 1,3, and 6 months.

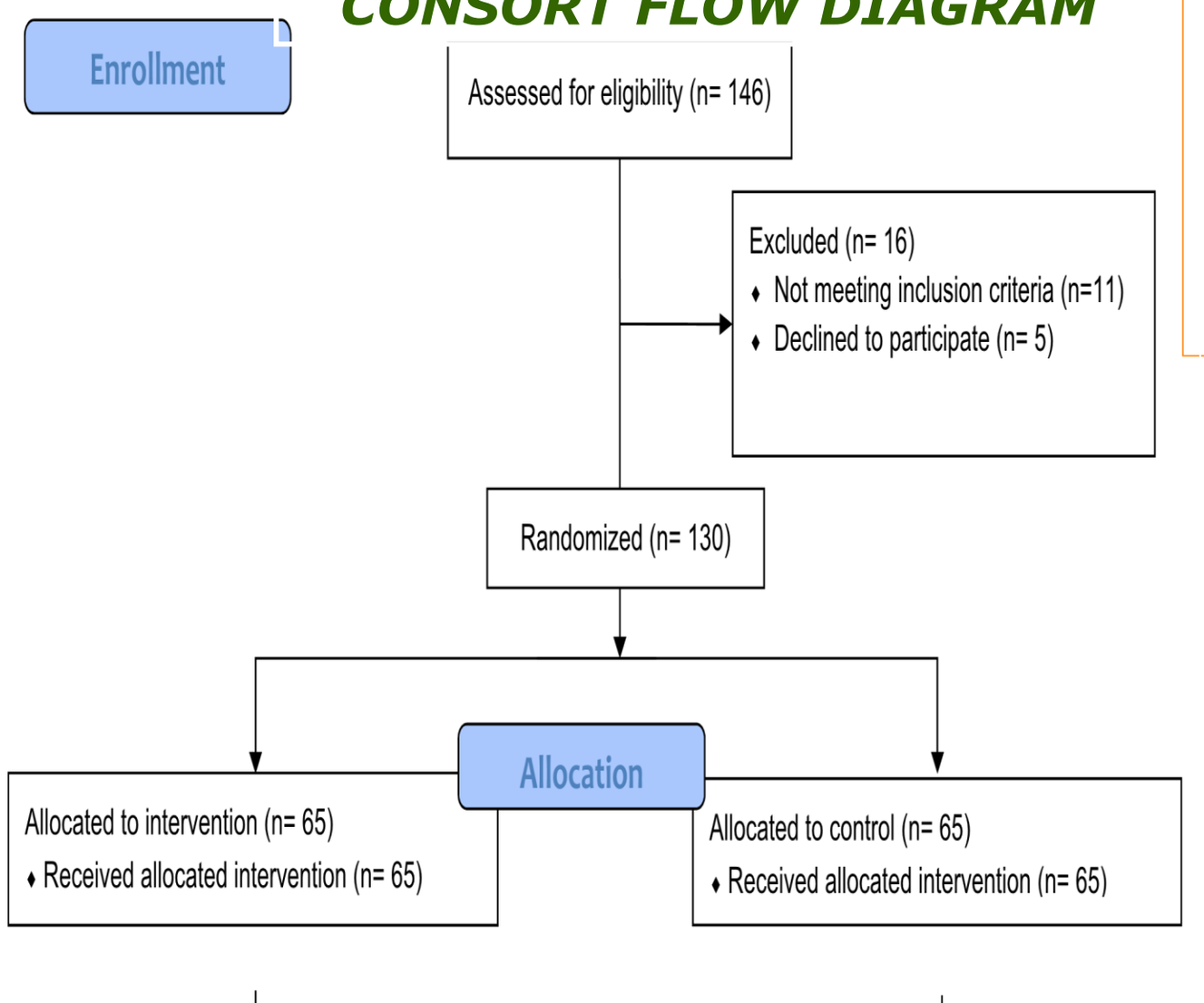
RESULT:





Whereas only **two** patient in placebo group had menstrual irregularities

CONSORT FLOW DIAGRAM



CONCLUSION: In this study **Ormeloxifene was not found to be effective in treatment of fibroadenoma and had concerning side effects.** (P value comparing complete and partial regression in both group is 0.54 and 0.45 respectively)

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