Essai Clinique

Généré le 09 mai 2025 à partir de

Titre	A Phase 3 Open-label Trial of Neoadjuvant Trastuzumab Deruxtecan (T-DXd) Monotherapy or T-DXd Followed by THP Compared to ddAC-THP in Participants With High-risk HER2-positive Early-stage Breast Cancer
Protocole ID	DESTINY-Breast11
ClinicalTrials.gov ID	NCT05113251
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Clinique
Médicament	Trastuzumab Deruxtecan (T-DXd) en monothérapie versus T-DXd suivi de THP versus ddAC-THP
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
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Statut	Fermé
But étude	The target population of interest in this study is participants with high-risk HER2-positive early-stage breast cancer. The purpose of this study is to determine the efficacy and safety of T-DXd neoadjuvant therapy. Participants will be randomised to one of 3 arms: T-DXd monotherapy (Arm A), T-DXd followed by THP (Arm B), or ddAC-THP (Arm C).
Critères d'éligibilité	• Patients must be at least 18 years of age. • Histologically documented HER2-positive early breast cancer (EBC) participants, including clinical stage at presentation (based on mammogram or breast MRI assessment): T0-4 (inclusive of inflammatory breast cancer), N1-3, M0 or ≥ T3, N0, M0 as determined by the AJCC staging system, 8th edition • ECOG performance status of 0 or 1 at randomization
Critères d'exclusion	• prior history of invasive breast cancer • stage IV breast cancer (determined by AJCC staging system) • any primary malignancy within 3 years (except resected non-melanoma skin cancer, curatively treated in situ disease) • history of DCIS (except those treated with mastectomy >5 years prior to current diagnosis) • History of, or current, ILD/pneumonitis • Prior systemic therapy for the treatment of breast cancer • Previous treatment with anthracyclines, cyclophosphamide or taxanes for any malignancy