Essai Clinique

Généré le 25 avr. 2024 à partir de

Titre	Initiative de Partenariat pour l'Évaluation d'innovations technologiques en RAdiothérapie (PERA)
Protocole ID	PERA
ClinicalTrials.gov ID	NCT03378856
Type(s) de cancer	Autre
Type étude	Autre
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
Investigateur principal	Dre Cynthia Ménard
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Statut	Actif en recrutement
Date d'activation	17-07-2017
But étude	The study consists of an effort to develop infrastructure that will support systematic collection of data from daily radiotherapy practice. At the core, PERA is a large observational cohort study, serving as a multiple cohort randomized trial and image banking facility. It includes consent for the collection of imaging data, patient-reported outcomes, and broad randomization for studies according to the innovative cohort multiple randomized controlled trial design (cmRCT).The basis of this design is a prospective cohort of participants receiving care as usual, who give informed consent for cohort participationParticipants can furthermore be asked for informed consent to be randomized in future RCTs conducted within the cohort. Participants are informed that they will be offered an experimental intervention if they are randomly selected. They are also informed that they otherwise might serve as controls without being notified and that their data can be used in a trial context. For each participant in the cohort, PROs are captured at baseline and at regular intervals during follow-up. Within this cohort, multiple RCTs can be conducted. The design is especially attractive for clinical research areas with rapid evolution of technology, and for highly desired or expensive interventions.In the first stage, at entry into the cohort, all potential participants are asked for their informed consent to participate in a cohort study and broad consent to be either randomly selected to be approached for experimental interventions or to serve as control without further notice during participation in the cohort. In a second stage, at the initiation of an RCT within the cohort, informed consent to receive the intervention is then only sought in those randomly selected for the intervention arm. At the third stage, after completion of each RCT, all cohort participants receive aggregate disclosure of trial results.
Critères d'éligibilité	• Ability to provide informed consent • Receiving radiotherapy or brachytherapy
Critères d'exclusion	