Trial registration data set :

Primary registry and trial identifying number	ClinicalTrials.gov NCT03305978
Date of registration in primary registry	September 26, 2017
Secondary identifying numbers	38RC17.132
Source(s) of monetary or material support	University Hospital, Grenoble
Primary sponsor	University Hospital, Grenoble
Secondary sponsor(s)	French Thoracic Imaging Society
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Public title	Pulmonary Nodule Detection: Comparison of an Ultra Low Dose vs Standard Scan.
Scientific title	Detection of Pulmonary Nodules: Comparison of Ultra-low-dose Chest CT (Approaching a Two Views Chest X-ray Radiation) and Standard Low Dose CT. A Monocentric, Prospective, Non-randomized, Comparative, Open-label Study With Blind Reading of the Judgment Criteria
Country of recruitment	France
Health condition(s) or problem(s) studied	Lung cancer screening, radiation exposure
Intervention(s)	Device: Ultra low dose chest CT An additional ultra low dose CT row is performed for every subject besides standard diagnostic low dose chest CT. Other Name: Revolution CT (GE Healthcare) 442507CN0, equiped with ASIR V
	Device: Low dose chest CT standard diagnostic low dose chest CT Other Name: Revolution CT (GE Healthcare)
Key inclusion and exclusion criteria	Ages eligible for study: ≥18 years Sexes eligible for study: both Accepts healthy volunteers: no
	Inclusion criteria : Patients referred for non enhanced chest CT for following indications : - lung nodule search or control - nodular abnormality on chest X ray - statement of COPD or emphysema - asbestos exposure - nodule localization before radio frequency ablation - assessment of disease extent of an extra thoracic cancer (in case of iodinated intravenous contrast agent contraindication) - statement before extrathoracic transplantation (in case of iodinated intravenous contrast agent contraindication) Affiliated with the french social security Who signed consent
	Exclusion criteria : Inability to lie down and stay still during the examination Inability to hold breath more than 5 seconds Pneumonia in the last 3 months Body mass index more than 35kg/m² exclusion period of another interventionnal study

	referred for articles L1121-5 to L1121-8 of french public health code Pregnant or breastfeeding women
Study type	Interventional
	Allocation: Non-Randomized Intervention Model: Sequential Assignment Intervention Model Description: Major Patient Addressed for Thoracic CT without Injection of Contrast Masking: Single (Outcomes Assessor) Masking Description: blinding evaluation of criteria
	Primary purpose: diagnostic
Date of first enrolment	October 3, 2017
Target sample size	150
Recruitment status	Recruiting
Primary outcome(s)	Ultra low dose CT lung nodule detection sensibility [Time Frame: 22 months] Detection rate (%) of ≥4mm lung nodules in ultra low dose chest CT versus standard low
Key secondary outcomes	- Ultra low dose CT diagnostic performances of lung nodule detection [Time Frame: 22 months] :true positives, false positives, true negatives, false negatives, positive predictive value, negative predictive value, specificity, of ≥4mm lung nodules detection within ultra low dose chest CT versus standard low dose chest CT - Concordance of ≥4mm lung nodules characteristics between ultra low dose and standard low dose chest CT [Time Frame: 22 months] : comparison of size, density, type (true nodule or intrapulmonary ganglion) of ≥4mm lung nodule between ultra low dose and standard low dose chest CT - Ultra low dose CT inter-observer reproducibility [Time Frame: 22 months] : inter observer reproducibility for size, density and type of ≥4mm lung nodule detected in ultra low dose CT - Influence of subjects characteristics, nodule location, and nodule size on detection between ultra low dose and standard low dose chest CT [Time Frame: 22 months] : analysis of subjects characteristics (age, gender, body mass index), ≥4mm nodule location, and ≥4 mm nodule size on detection between ultra low dose and standard low dose chest CT - Concordance of emphysema characteristics between ultra low dose and standard low dose chest CT [Time Frame: 22 months] : comparison of emphysema detection, type (centrilobular, paraseptal, panlobular, bullous) and distribution between ultra low dose and standard low dose chest CT - Concordance of coronary calcification detection and quantification between ultra low dose and standard low dose chest CT [Time Frame: 22 months] : Comparison of Weston scores between ultra low dose and standard low dose chest CT - Concordance of bronchial abnormalities evaluation between ultra low dose and standard low dose chest CT [Time Frame: 22 months] : comparison of detection of bronchial thickening or dilatation between ultra low dose and standard low dose chest CT
Ethics Review	approved by the relevant ethical committee (Comité de Protection des Personnes, CPP Sud-Est VI, France, CPP Reference: AU1342), on July 7, 2017