Clinical Trial Protocol

Patient-Customized Bioprinting Technology for Practical Regeneration of the Respiratory Tract (Trachea)

Protocol No.	:	3D Bioprinting Trachea
Protocol Version	:	2.3
Development date	:	2023-05-26

CLINICAL TRIAL PROTOCOL: CLINICAL RESEARCH PLAN OVERVIEW

Professor Bae Ja-sung, Seoul St. Mary's Hospital **Patient-Customized Bioprinting Technology for Practical Regeneration of the Respiratory Tract (Trachea)**	가톨릭대학교 서울성모병원 THE CATHOLIC UNIV. OF KOREA SEOUL ST. MARY'S HOSPITAL		
Study Title	Patient-Customized Bioprinting Technology for Practical Regeneration of the Respiratory Tract (Trachea)		
Principal Investigator	Professor Bae Ja-sung, Catholic University of Korea, Seoul St. Mary's Hospital		
Clinical Research Institution	Catholic University of Korea, Seoul St. Mary's Hospital		
Reference	Bae Ja-sung, et al. Rational Tissue Engineering Strategy for Extensive Circumferential Tracheal Reconstruction Using Three-Dimensional (3D) Printing. Biomaterials. 2018;185:276-283.		
Period	72 months from IRB approval date	**Stage**	Cell therapy phase for academic purposes
Objective	This clinical study aims to assess the effectiveness and safety of transplanting 3D patient-specific bioprinted tracheal organs using biopolymers, hydrogels, and tissue regeneration cells for respiratory tract regeneration.		
Methods	Participants with thyroid or airway diseases necessitating partial or segmental resection will be enrolled after providing written consent. Screening tests will determine eligibility. The 3D bioprinted trachea, incorporating stem cells from the nasal cavity and nasal septum cartilage, will be transplanted. Evaluation includes endoscopy, bronchoscopy, CT, and lab tests. Neck fixing splints will stabilize transplanted areas post-surgery. Thyroid cancer patients will have extended follow-up with specific tests.		
Number of Participants	1		
Target Disease	Congenital tracheal softening, traumatic tracheal stenosis, tracheal defects post-thyroid cancer surgery, requiring partial or segmental resection		
Selection/Exclusion Criteria	Selection Criteria: ● Adults aged 19-75 ● Patients meeting criteria for thyroid or airway disease requiring resection ● Patients with thyroid cancer invading the trachea, requiring resection with expected organ dysfunction post-surgery ● Patients with organ defects around cartilage (>30%), suitable for 3D bioprinting ● Female participants using contraception during the study ● Participants providing informed consent		

	Exclusion Criteria: ● Pregnant or lactating women ● Prior thyroid or airway peripheral surgery ● Inflammation of thyroid or surrounding tissues ● Systemic inflammatory disease ● High risk due to liver, kidney, or heart disease ● Sepsis or hemorrhagic predisposition ● Prior radiotherapy to head/neck ● Recent use of other research medications/devices ● History of cell therapy ● Malignant tumors other than thyroid cancer ● Other deemed inappropriate for the study
Product Description	3D cell-printed trachea using patient-specific cells (hNTSCs, hNCs) and hydrogels Patient-specific single-product bioprinted trachea No artificial genetic manipulation
Validity Assessment	Primary Variables: ● Endoscopic findings after 1, 2, 4, and 24 weeks ● Airway intraluminal clearance rate ● Degree of granuloma and bark formation ● Inflammation and other findings Secondary outcome ● CT-based airway condition comparison ● Postoperative inflammatory levels (WBC, WBC Diff, CRP, ESR) ● Bronchoscopy findings (wall stability, tracheal opening, mucosal formation, inflammation/granulation)
Safety Assessment	Abnormal responses, vital signs, ECG, lab tests, physical exam