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Comparison of ultra-low-dose versus standard-dose computed tomography for esophageal foreign body detection

Submission date 26/03/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 31/03/2026	**Overall study status** Completed	
Last Edited 30/03/2026	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
Prospective comparison of ultra-low-dose versus standard-dose computed tomography for esophageal foreign body detection

Study objectives

This study aimed to address these knowledge gaps by conducting a prospective comparison of ultra-low-dose CT (ULD-CT) and standard-dose CT (SD-CT) for EFB detection.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/04/2025, Ethics Committee of The First Hospital of Hebei Medical University (No. 89 Donggang Road, Yuhua District, Shijiazhuang, 050000, China; +86 (0)311-87156182; 1861123450@163.com), ref: [2025]YS-062

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Dose comparison

Assignment
Parallel

Purpose
Diagnostic

Study type(s)

Health condition(s) or problem(s) studied
Patients suspected of swallowing esophageal foreign body (EFB)

Interventions
Patients will be randomized to ULD-CT (100 kV/50 mA, adaptive statistical iterative reconstruction-V 80% + deep learning image reconstruction) or SD-CT (120 kV/200 mA, filtered back projection + adaptive statistical iterative reconstruction-V 30%) groups.

Patient randomization is performed using a computer-generated sequence with permuted blocks of varying sizes (4, 6, and 8) stratified by age group (pediatric <18 years vs adult ≥18 years) and the participating center. Allocation concealment is maintained through sealed opaque envelopes opened immediately prior to CT scanning. All image interpreters, endoscopists, and surgeons are blinded to the CT protocol assignment.

All examinations are performed on 256-slice multi-detector CT scanners with deep-learning reconstruction capabilities . Patients are positioned supine with their arms elevated above the head when possible. No oral contrast is administered to avoid obscuring foreign bodies or delaying endoscopy.

The SD-CT protocol will utilize parameters consistent with routine chest CT at participating institutions: a tube voltage of 120 kV, a reference tube current of 200 mA with automatic tube current modulation (ATCM) enabled, a rotation time of 0.5 seconds, a pitch of 0.992, and collimation of 0.625 mm. Images are reconstructed using filtered back projection with 30% adaptive statistical iterative reconstruction blending, representing the current clinical standard at participating sites. The rationale for 120 kV is based on standard thoracic imaging protocols optimized for general diagnostic purposes.

The ULD-CT protocol will employ aggressive dose reduction strategies: a tube voltage of 100 kV, a reference tube current of 50 mA with ATCM (range 10–80 mA), and an identical rotation time and pitch to that of the SD protocol. The 100 kV/50 mA parameters are selected based on preliminary phantom studies demonstrating maintained foreign body conspicuity at these settings when combined with advanced reconstruction. Raw data are reconstructed using 80% adaptive statistical iterative reconstruction blending, followed by DLIR at medium strength.

For both protocols, images will be reconstructed at a 0.625-mm slice thickness with a 0.5-mm overlap to enable multiplanar reformations. The scan range will extend from the lower neck (C3 level) through the gastroesophageal junction, with careful positioning to minimize breast tissue inclusion in female patients. Dose reduction features, including organ-based tube current modulation and adaptive collimation, will be enabled for all scans.

Intervention Type
Other

Primary outcome(s)
1. Image quality measured using a medical physicist blinded to the protocol assignment. The signal-to-noise ratio (SNR) was calculated as the mean attenuation of the descending aorta divided by the standard deviation of subcutaneous fat. The contrast-to-noise ratio was calculated as the difference in attenuation between aortic blood and paraspinal muscle divided by image noise. To better align with the diagnostic task, additional measurements were performed in paraesophageal fat. Measurements were performed on axial images at three standardized levels (aortic arch, carina, and mid-esophagus) with circular regions of interest (150 mm^2) placed consistently using anatomical landmarks. Subjective image quality was independently assessed by two thoracic radiologists with 8 and 12 years of experience. Images were reviewed on diagnostic workstations (window width: 350 HU, window level: 40 HU for soft tissue; window width: 1,500 HU, window level: –600 HU for lung evaluation). Readers scored the following parameters on a 5-point Likert scale: (1) edge definition of the mediastinal structures; (2) image noise; (3) diagnostic confidence for foreign body detection; and (4) overall diagnostic quality. A score ≥3 was considered diagnostically acceptable. Discrepancies between readers were resolved through consensus review, with the consensus score used for analysis. Inter-reader agreement was assessed using weighted kappa statistics. Measured at CT scanning.

2. Radiation dose metrics measured using the scanner-reported volume CT dose index (CTDIvol) and dose-length product. The effective dose (ED) was calculated using age- and sex-specific conversion factors ($k = 0.014$ $mSv \cdot mGy^{-1} \cdot cm^{-1}$ for adults; age-adjusted factors for pediatric patients based on International Commission on Radiological Protection recommendations [Publication 103]). Size-specific dose estimates were calculated using patient anteroposterior and lateral dimensions measured at the mid-chest level. Measured at CT scanning.

Key secondary outcome(s)

Completion date

25/09/2025

Eligibility

Key inclusion criteria
1. Patients aged 3–80 years
2. A history of foreign body ingestion within 6 hours of presentation
3. Symptoms suggestive of esophageal impaction, including dysphagia, odynophagia, chest pain, or hypersalivation
4. Planned endoscopic or surgical evaluation within 12 hours of CT imaging

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
3 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
180

Key exclusion criteria
1. Severe cardiorespiratory instability requiring immediate intervention
2. Pregnancy or a positive pregnancy test
3. A known contrast allergy (for enhanced scans when clinically indicated)
4. Prior esophageal surgery or known esophageal stricture
5. Metallic implants causing substantial artifacts affecting >30% of the esophageal evaluation area
6. Body mass index (BMI) >40 kg/m² (due to potential image quality degradation at ultra-low doses)

Date of first enrolment
18/01/2024

Date of final enrolment
26/06/2025

Locations

Countries of recruitment
China

Sponsor information

Organisation
First Affiliated Hospital of Hebei Medical University

ROR
https://ror.org/04z3aby64

Funder(s)

Funder type

Funder Name
Hebei Province Medical Science Research Key Project

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available