

## CLINICALTRIALS.GOV STUDY DOCUMENT

Official Study Title

*Comparative Evaluation of Contrast-Enhanced MRI and FDG-PET/CT in Spinal Pathology: Image Quality and Short-Term Renal-Hematologic Safety*

### Protocol ID

DDMFDW6dc1

### ClinicalTrials.gov Identifier (NCT Number)

Not Yet Assigned

### Document Type

Study Protocol

### Date of Document

June 2026

### Institution

Cairo University

### Principal Investigator

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## Materials and Methods

**Figure 1.** CONSORT-style flowchart of patient allocation to MRI (n=60) and FDG-PET/CT (n=60) groups with stratification by spinal region (cervical n=60, lumbar n=60) and age ( $\leq 50$ y n=60,  $>50$ y n=60) (n=15 per subgroup). Primary endpoints: image quality (SNR/CNR/VGA) and safety (BUN/eGFR/hemoglobin).

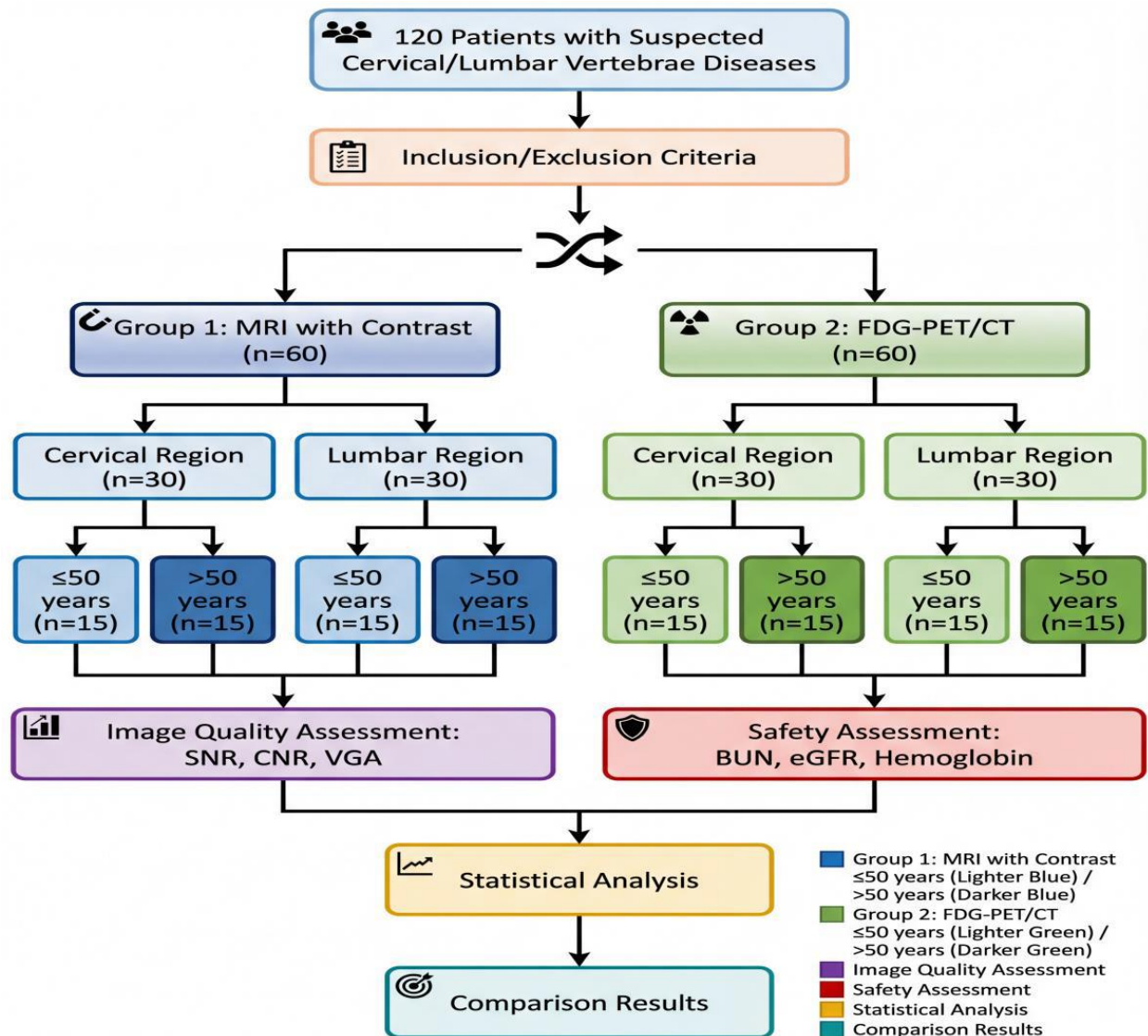
### 2.1 Study Design and Ethical Considerations

This was a prospective, non-randomized, comparative observational study designed to evaluate and compare the image quality and short-term physiological profiles of two routinely used

diagnostic imaging modalities: contrast-enhanced MRI and FDG-PET/CT. The study was (non-interventional);

no experimental treatments, novel diagnostic agents, or deviations from standard clinical protocols were introduced. All imaging procedures, contrast administrations, and safety measures were performed strictly according to established institutional and manufacturer guidelines for routine clinical care. The study was approved by the Institutional Review Board of Qassim University (Reference No. IRB-576/11-9/2024; MISR University Scientific Research Innovation Committee, 10/02/2025), and

written informed consent was obtained from all participants.



(Figure 1).

Sequential allocation achieved excellent baseline balance (Table 2: all  $p > 0.05$ ), supporting valid image quality comparisons despite non-randomization.

#### **Patient Population and Sample Size Justification**

A total of 120 consecutive patients with clinically indicated cervical or lumbar spinal pathologies were enrolled. Patients were sequentially allocated to undergo either contrast-enhanced MRI ( $n=60$ ) or FDG-PET/CT ( $n=60$ ) based on real-world clinical scheduling and scanner availability, reflecting practical clinical workflow where strict randomization is often precluded by modality-specific contraindications and patient logistics. This sequential, non-randomized allocation resulted in well-balanced baseline demographic and clinical characteristics between groups (Table 2, all  $p > 0.05$ ), supporting the validity of the comparative image quality analysis.

#### **Patient Matching and Scanner Standardization**

Scans acquired on identical 3T MRI/PET/CT scanners (same protocol). Patients matched for degenerative grade (Pfirrmann 2-3). Marrow fat fraction controlled via T1 mapping. All analyses adjusted for scanner time/batch effects.

#### **Imaging Protocols**

##### **1. MRI Protocol:**

Imaging was performed using a 3T Siemens Trio TIM scanner with a dedicated spinal coil. Acquired sequences included sagittal and axial T1-weighted and T2-weighted images (slice thickness 3-4 mm, field of view 250-350 mm). [13].

Following non-contrast sequences, the standard clinical metabolic tracer gadobutrol was administered intravenously at the routine diagnostic dose of 0.1 mmol/kg, with strict adherence to established contraindications and safety protocols

##### **2. PET/CT with FDG**

Patients fasted for a minimum of 6 hours prior to the scan, with blood glucose levels confirmed to be  $< 150$  mg/dL. The radiopharmaceutical F-18 FDG (4 MBq/kg, PETNET Solutions) was administered intravenously. Standard post-scan radiation safety precautions were advised for a period of 6-12 hours.

Table 1 . presents complete acquisition parameters. PET/CT used non-contrast CT for attenuation correction only. Results 'with vs without contrast' refers exclusively to MRI gadobutrol administration

Table 1. Standardized MRI Protocol				PET/CT Protocol	
Imaging Protocols for MRI and FDG-PET/CT in Cervical and Lumbar Spine Evaluation Parameter					
Scanner	3T	Siemens	Trio	TIM	Siemens Biograph mCT / GE Discovery MI
	(spinal coil)				

Sequences/Acquisition	Sagittal/axial weighted	T1/T2-	Emission: 3 min/bed × 7 beds (21 min total)
Slice Thickness/Voxel	3–4 mm		2 × 2 × 2 mm
FOV/Matrix	250–350 mm		400 × 400
Scan Range	Lumbosacral spine		Vertex to mid-thigh
Contrast/Radiotracer	Gadobutrol 0.1 mmol/kg IV		<sup>18</sup> F-FDG 3.7 MBq/kg IV
Contrast Timing	Post sequences	non-contrast	Uptake: 60 ± 5 min
CT Parameters	-		100 kVp, 100 mAs, CARE Dose4D, NON-CONTRAST
Reconstruction	Standard		OSEM 4i16s TOF, 4 mm Gaussian filter
Attenuation Correction	-		CT-based ( $\mu = 0.1 \text{ cm}^{-1}$ )
Radiation Dose	-		~8 mSv
Other Notes	Safety monitoring protocols	per	Radiation precautions 6–12 h post-scan