

# A Contrast Medium Sparing Strategy Using Automated CO2 Injection During PVI for Prevention of Major Adverse Kidney Events (MAKE)

NCT06656988

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Status	RECRUITING
Phase	Phase 3
Sponsor	University of Leipzig
Enrollment	1,960 participants

## Key Eligibility Criteria

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### Inclusion (6)

- Symptomatic peripheral arterial disease presenting with either acute symptoms (Rutherford clinical categories I-IIb) or chronic symptoms (Fontaine stages IIb-IV or Rutherford clinical categories 2-6)
- Planned peripheral vascular intervention of infrainguinal arteries due to femoropopliteal and/or infrapopliteal lesions
- Increased risk of CA-AKI identified by a baseline risk score of  $\geq 5$  points based on a published dedicated PVI risk score and a pre-angiographic estimated glomerular filtration rate (eGFR)  $\leq 60$  ml/min/1.73 m<sup>2</sup>
- Both angiographic strategies seem feasible at the investigator's discretion
- Age 18 years or older

... and 1 more (see full listing online)

### Exclusion (21)

- Very agitated patients
- Patients with planned full anaesthesia during procedure
- Patients with a life-expectancy less than one year
- Patients confined to bed that are completely non-ambulatory
- Known acute renal failure or known unstable renal function as evidenced by a recent increase in serum creatinine (SCr) of  $\geq 0.5$  mg/dl or  $\geq 25\%$  within 7 days

... and 16 more (see full listing online)

## Locations (11 total)

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Tirol Kliniken Innsbruck, Innsbruck, Austria  
Universitätsklinik für Innere Medizin II, Vienna, Austria  
Kreiskrankenhaus Alsfeld, Alsfeld, Germany

... and 8 more locations