

# To Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of KN060 in ESRD Dialysis Patients

NCT07201467

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Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Suzhou Alphamab Co., Ltd.
Enrollment	12 participants

## Key Eligibility Criteria

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### Inclusion (7)

- Male or female subjects aged between 18 and 80 years (inclusive);
- $\text{kg/m}^2 < \text{BMI} < 28 \text{ kg/m}^2$  ;
- Diagnosis of ESRD and be receiving regular, stable hemodialysis treatment within the three months prior to screening: dialysis is performed through a functional, non-infected graft arteriovenous fistula / autologous arteriovenous fistula ( AVG/AVF ) ; dialysis is performed three times per week, with at least 3.5 hours per session ( at least 75% of dialysis sessions within the four weeks prior to randomization meet the this criteria) ;
- The clinical status of the underlying ESRD is stable (assessed by the investigator) ;
- $\text{Kt/V} \geq 1.2$  within 3 months before screening ;
- ... and 2 more (see full listing online)

### Exclusion (6)

- A history of malignant tumor;
- History of mechanical/artificial heart valve replacement surgery;
- History of major medical events within 3 months before screening , such as acute coronary syndrome, stroke , major organ bleeding, acute heart failure, systemic thromboembolic events , major surgery, etc. , or history of AVF/AVG functional loss;
- Using anticoagulant/antiplatelet drugs due to disease treatment , such as warfarin , dabigatran, rivaroxaban , clopidogrel , or aspirin  $>100 \text{ mg/day}$  (investigators are allowed to use heparin / low molecular weight heparin during dialysis, depending on the situation );
- There is a high risk of bleeding, or abnormal bleeding-related indicators:
- ... and 1 more (see full listing online)

## Locations (1 total)

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Peking University People's Hospital, Beijing, Beijing Municipality, China