

DRug-coAted Balloon Compared With cuttinG balloON in Treatment of Arteriovenous Fistula Stenosis

NCT06527963

Status	RECRUITING
Sponsor	RenJi Hospital
Enrollment	180 participants

Key Eligibility Criteria

Inclusion (3)

- Subjects aged between 18 and 75 years. Subjects possess a mature upper limb autologous arteriovenous fistula (AVF) and have undergone at least one hemodialysis session.
- Target lesion must be located in the venous segment of the upper limb AVF. Doppler ultrasound confirms that the target lesion stenosis is $\geq 50\%$, accompanied by at least one of the following clinical manifestations: elevated venous pressure during dialysis, abnormal fistula signs, significant reduction in blood flow ($< 200\text{ml/min}$).
- Guidewire and balloon successfully pass through the lesion and complete dilation. 6. Subjects or their legal representatives must understand the purpose of the trial, voluntarily participate in the clinical trial, and sign an informed consent form, while also being willing to adhere to the specific follow-up schedules set by this trial.

Exclusion (6)

- Target lesion located in the arterial segment or anastomosis of the AVF. Target lesion located in the lower limb AVF. Subjects with previous stent implantation in the AVF. Patients diagnosed with symptomatic central venous occlusive disease: AVF flow reduction accompanied by swelling of the ipsilateral limb, chest, or facial area, with DSA confirmation of central venous occlusive disease.
- Subjects with two or more target lesions in the AVF (when two stenoses are less than 3 cm apart, they are considered as one target lesion).
- Subjects with acute thrombosis in the AVF or who have undergone AVF thrombolysis or thrombectomy within the past 30 days.
- Subjects who have undergone or plan to undergo surgical intervention on the AVF within 30 days.
- Subjects with AVF infection or concurrent systemic active infection. Subjects planning renal transplantation or switching to peritoneal dialysis within the next 12 months.

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

Locations (3 total)

First Affiliated Hospital of Zhengzhou University, Zhengzhou, Henan, China
The Second Affiliated Hospital of Nanjing Medical University, Nanjing, Jiangsu, China
Renji Hospital, Shanghai, Shanghai Municipality, China