

# Ultrasound-guided needle placement for dialysis access

<b>Submission date</b> 10/11/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/11/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/11/2025	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

This study is testing a new device that helps dialysis staff place the first dialysis needle. The device shows the location of your access (fistula) and gives real-time guidance to help line up the needle and enter the vessel. The study will check if using the device is feasible and safe, with the main goal of seeing whether one needle can be placed successfully.

### Who can participate?

Patients (not pregnant or breastfeeding) aged 18 and older who are currently undergoing dialysis.

### What does the study involve?

Participation will be very brief—only about one to three minutes during the regular dialysis session. The device will be used by the dialysis nurse or technician to help guide the placement of one needle. It will not change the treatment or extend the dialysis time, and it fits naturally into the usual care routine. Participation is complete once the dialysis session is finished.

### What are the possible benefits and risks of participating?

**Benefits:** Participants may not receive direct medical benefits. What is learnt could help improve future tools for safer, more accurate needle placement and potentially reduce complications over time.

**Risks:** The risks are the same as routine cannulation, such as pain, bruising, bleeding, infiltration, or missed sticks.

### Where is the study run from?

The study is run from Uzbekistan.

### When is the study starting and how long is it expected to run for?

The study is expected to run for one month in October 2025.

### Who is funding the study?

X9, Inc.

Who is the main contact?  
Rachel Walsh at X9, inc., Rwalsh@x9med.com

## Contact information

### Type(s)

Public, Scientific

### Contact name

None Rachel Walsh

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Principal investigator

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## Additional identifiers

### Protocol serial number

CP-00001

## Study information

### Scientific Title

Ultrasound-guided power-assisted needle insertion for vascular access

### Acronym

ACCESS-1

### Study objectives

The primary objective of the study is to evaluate successful insertion of one dialysis needle into the AVF for cannulation.

**Ethics approval required**

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**Ethics approval(s)**

approved 16/10/2025, Ethics Committee affiliated with the Ministry of Health of Uzbekistan (Tashkent, 100015, Aybek str., 45, Tashkent, 100015, Uzbekistan; +(99871) 256-37-38, 256-14-89; info@minzdrav.uz), ref: 10/1-2202

**Primary study design**

Interventional

**Allocation**

N/A: single arm study

**Masking**

Open (masking not used)

**Control**

Uncontrolled

**Assignment**

Single

**Purpose**

Device feasibility

**Study type(s)**

Efficacy, Safety

**Health condition(s) or problem(s) studied**

Patients undergoing dialysis for end stage renal disease.

**Interventions**

Each participant will have the study device used once during a single dialysis session. The device assists the dialysis nurse or technician in inserting one of the dialysis needles by identifying the location of the vascular access (fistula) and providing ultrasound and AI-based localization guidance to deliver accurate needle placement for dialysis cannulation. The duration of exposure to the device is expected to be brief, lasting approximately one to three minutes.

**Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Ultrasound-Guided, Power-Assisted Needle Insertion

**Primary outcome(s)**

1. Proportion of procedures in which the dialysis needle is successfully inserted into the AVF within three attempts measured using the confirmation of blood flashback at one cannulation procedure

Proportion of procedures in which the dialysis needle is successfully inserted into the AVF within three attempts, as confirmed by blood flashback during one cannulation procedure.

### **Key secondary outcome(s)**

1. Absence of serious adverse events (SAEs) related to the investigational device measured using data collected from electronic Case Report Forms (eCRF) at one cannulation procedure

Absence of serious adverse events (SAEs) related to the investigational device during one cannulation procedure.

### **Completion date**

26/10/2025

## **Eligibility**

### **Key inclusion criteria**

1. Males or non-pregnant, non-breastfeeding females  $\geq 18$  years of age
2. Presence of an upper extremity arteriovenous fistula (AVF) access site in the forearm or upper arm
3. AVF is actively used for dialysis treatment
4. AVF diameter is between 8 mm and 12mm, confirmed by ultrasound
5. AVF is  $\leq 6$  mm below the surface of the skin, confirmed by ultrasound
6. Able to understand and complete a pain questionnaire
7. Able and willing to provide written informed consent

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

18 years

### **Upper age limit**

70 years

### **Sex**

All

### **Total final enrolment**

7

## Key exclusion criteria

1. Arteriovenous graft (AVG) is actively used for dialysis treatment.
2. Presence of known (pseudo-)aneurysms, stenosis, thrombosis or stents in the AVF access site
3. Presence of a condition or impediment that may interfere with ultrasound imaging

## Date of first enrolment

16/10/2025

## Date of final enrolment

26/10/2025

# Locations

## Countries of recruitment

Uzbekistan

## Study participating centre

Territorial Medical Association of Yangiyul District

10 Guncha Street

Yangiyul

Uzbekistan

100095

# Sponsor information

## Organisation

X9, Inc.

# Funder(s)

## Funder type

Not defined

## Funder Name

X9, Inc.

# Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>			18/11/2025	No	No