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Ultrasound-guided needle placement for dialysis access

Submission date	Recruitment status	[_] Prospectively registered
10/11/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/11/2025	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/04/2026	Urological and Genital Diseases	

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

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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
Ethics approval required

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 ≥ 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 ≤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?
Results article		07/04/2026	08/04/2026	Yes	No
Basic results			18/11/2025	No	No