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A study of electrical stimulation of a nerve in the penis to improve bladder control in people with bladder problems caused by spinal cord injury

Submission date
28/09/2026

Recruitment status
No longer recruiting

Registration date
29/09/2026

Overall study status
Completed

Last Edited
28/09/2026

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
A spinal cord injury can damage the nerves that control the bladder. This can lead to a condition called neurogenic bladder, where a person has problems storing or passing urine. In some people, the bladder muscle may contract when it should not, which can cause problems with bladder control.
Electrical stimulation uses small electrical signals to activate nerves. This study looked at whether electrical stimulation of a nerve in the genital area could safely improve bladder function in people with neurogenic bladder after a spinal cord injury. The researchers looked at how much urine the bladder could hold, pressure inside the bladder and how well the bladder could stretch as it filled.

Who can participate?
People aged 20 to 70 years with neurogenic bladder following a spinal cord injury could take part. Participants needed to have a spinal cord injury between the T1 and L2 levels of the spine and to have received drug treatment that had not worked for 6 months. People could not take part if they had certain other neurological conditions, serious medical or surgical complications, urinary tract stones, bladder tumours or narrowing of the tubes that carry urine from the kidneys to the bladder.

What does the study involve?
All participants received electrical nerve stimulation using a device called the UCon Nerve Stimulator. A patch electrode was placed on the skin over the genital nerve area and another electrode was placed on the lower abdomen. The device then delivered small electrical signals. The strength of the stimulation was adjusted for each participant according to what they could comfortably tolerate and how their bladder responded.
Participants received one supervised treatment session lasting 30 minutes each day for 14 days in a row. Where possible, they continued their usual method of managing their bladder during the study. Everyone received the same treatment, so there was no comparison or placebo group.

Bladder function was tested before treatment and 24 hours after the final treatment session. These tests measured how much urine the bladder could hold, the pressure produced by the bladder muscle and how well the bladder could stretch while filling. During these tests, measurements were taken with the nerve stimulation switched both off and on. This allowed the researchers to examine the immediate effects of stimulation. Participants were followed for safety for 8 weeks after stimulation ended.

What are the possible benefits and risks of participating?
Participants may have experienced improvements in bladder function, although there was no guarantee that the treatment would help them personally. The study may also provide information that could help researchers understand whether this type of electrical nerve stimulation could be useful for people with neurogenic bladder after spinal cord injury.
The information provided does not specify the individual risks or side effects expected from the treatment. The researchers monitored participants for treatment-related adverse events, meaning unwanted medical problems that occurred during treatment, from the first stimulation session until the end of the 8-week follow-up period.

Where is the study run from?
The study was run in China and was sponsored by The Fifth Affiliated Hospital of Zhengzhou University in Zhengzhou, China.

When is the study starting and how long is it expected to run for?
December 2024 toOctober 2025.

Who is funding the study?
The study was funded by the Henan Provincial Department of Human Resources and Social Security and the Department of Science and Technology of Henan Province.

Who is the main contact?
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Study information

Scientific Title
Clinical study of percutaneous electrical stimulation of the dorsal penile nerve in the treatment of neurogenic bladder after spinal cord injury

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/01/2024, Medical Ethics Committee of The Fifth Affiliated Hospital of Zhengzhou University (No.3 Kangfuqian Street, Erqi District, Zhengzhou, 450052, China; +86 371 6128 5376; wfyllwyh@163.com), ref: KY20240101

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Device feasibility, Treatment

Study type(s)

Health condition(s) or problem(s) studied

Neurogenic bladder following spinal cord injury

Interventions
Participants received transcutaneous dorsal genital nerve stimulation using the UCon device at a frequency of 20 Hz and a pulse width of 200 μs. Stimulation intensity was individualized to 15–25 mA based on tolerability and the urodynamic response observed at baseline. Stimulation was administered under inpatient supervision once daily for 30 minutes on 14 consecutive days. The stimulation electrode was positioned over the dorsal or root region of the penis in male participants and above the clitoris or on the overlying skin fold in female participants. The return electrode was placed on the lower abdomen below the umbilicus. Participants maintained their usual bladder-management regimen whenever clinically feasible. This was a single-arm study with no concurrent control group.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
UCon Nerve Stimulator

Primary outcome(s)
1. Cystometric capacity measured using filling cystometry (mL) at baseline before the intervention and 24 hours after the final stimulation session, with acute DGNS-ON versus DGNS-OFF responses evaluated during both assessments

2. Maximum detrusor pressure during bladder filling measured using filling cystometry, measured as maximum Pdet in cmH_2O, where Pdet = Pves – Pabd at baseline before the intervention and 24 hours after the final stimulation session, with acute DGNS-ON versus DGNS-OFF responses evaluated during both assessments

3. Bladder compliance measured using filling cystometry, calculated as $\Delta V/\Delta Pdet$ and expressed in mL/cmH_2O at baseline before the intervention and 24 hours after the final stimulation session, with acute DGNS-ON versus DGNS-OFF responses evaluated during both assessments

4. Treatment-related adverse events measured using patient records at from the first stimulation session through completion of the 8-week post-stimulation follow-up

Key secondary outcome(s)

Completion date
20/10/2025

Eligibility

Key inclusion criteria
1. Drug therapy has been ineffective for 6 months
2. Has a definite diagnosis of neurogenic bladder, with consistent chief complaints, physical examination findings and imaging findings
3. Has a spinal cord injury between the T1 and L2 levels

4. Has no other neurological diseases or severe medical or surgical complications
5. Has complete pre-treatment and post-treatment data

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
20 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
22

Key exclusion criteria
1. Patients who refused Ucon treatment
2. Patients with urinary tract stones, bladder tumors, or ureteral strictures
3. Patients with incomplete pre- and post-operative data

Date of first enrolment
11/12/2024

Date of final enrolment
10/07/2025

Locations

Countries of recruitment
China

Sponsor information

Organisation
The Fifth Affiliated Hospital of Zhengzhou University

Funder(s)

Funder type

Funder Name
Henan Provincial Department of Human Resources and Social Security

Funder Name
Department of Science and Technology of Henan Province

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available