ISRCTN25722640 https://doi.org/10.1186/ISRCTN25722640

Hyperbaric oxygen therapy as a treatment for men with severe erectile dysfunction unresponsive to standard medications

Submission date	Recruitment status	[_] Prospectively registered
08/11/2026	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/11/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/11/2026	Urological and Genital Diseases	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific, Principal investigator, Public

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Additional identifiers

Study information

Scientific Title

Hyperbaric oxygen therapy in vascular erectile dysfunction refractory to phosphodiesterase-5 inhibitors: a single-center, randomized, double-blind, placebo-controlled trial with a 12-month follow-up

Acronym
DE-NOVO

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/10/2026, L'Ombudsman Uke (via delle olimpiadi 4, Enna, 94100, Italy; +39 935 /536536; protocollo@unikore.it), ref: 32375

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Placebo

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Vascular erectile dysfunction

Interventions
Active Arm: Patients receive 40 sessions of Hyperbaric Oxygen Therapy (HBOT) at 2.5 atmospheres absolute (ATA). Each session lasts 90 minutes and treatments are performed 5 days a week until the 40-session cycle is completed.
Control/Placebo Arm: Patients receive a sham treatment consisting of 40 sessions in the hyperbaric chamber at 1.1 ATA to ensure blinding. Each session lasts 90 minutes, 5 days a week.
Follow-up: Clinical evaluations (using the IIEF-5 questionnaire) and penile Doppler ultrasound (to measure Peak Systolic Velocity) are performed at baseline, and subsequently at 3, 6, and 12

months for all study arms.
Randomisation: Patients were randomly assigned to the two treatment arms in a 2:1 ratio (treatment vs. control).

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Penile vascular function and response to iPDE5 measured using IIEF5 and penile vascular doppler at 0, 3, 6 and 12 months

Key secondary outcome(s)

Completion date
30/11/2027

Eligibility

Key inclusion criteria
1. At least 6 months of severe vascular erectile disfunction
2. Erectile disfunction non responders to PDE5i
3. Difficulties in penetrating
4. Normal LH, FSH, Testosterone levels

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
50 Years

Upper age limit
70 Years

Sex
Male

Total final enrolment
200

Key exclusion criteria
1. Non vascular erectile disfunction
2. Abnormalities in LH, FSH, Testosterone levels

Date of first enrolment
09/11/2026

Date of final enrolment

08/04/2027

Locations

Countries of recruitment
Italy

Sponsor information

Organisation
Cannizzaro Hospital of Catania

Organisation
Kore University of Enna

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

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?
Participant information sheet			10/11/2026	No	Yes