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Comparison of different shock wave therapies in the treatment of erectile dysfunction

Submission date
10/10/2025

Recruitment status
No longer recruiting

Registration date
10/10/2025

Overall study status
Completed

Last Edited
10/10/2025

Condition category
Urological and Genital 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
Erectile dysfunction (ED) is the inability to get or keep an erection firm enough for sexual activity. It is a common condition, affecting up to half of men aged between 40 and 70 years. One of the newer treatments for ED uses shock waves called shockwave therapy to improve blood flow in the penis. There are two main types of this treatment: focused shockwave therapy (fSWT) and radial wave therapy (rWT). Both are believed to stimulate the growth of new blood vessels and improve tissue health. The aim of this study is to compare the long-term effectiveness of these two methods in improving erectile function in men with blood vessel related ED.

Who can participate?
Men aged 40 to 70 years who have had erectile dysfunction for at least 3 months and have a moderate to severe reduction in erectile function

What does the study involve?
This was a two-centre prospective cohort study, meaning men were treated and followed over time in two different hospitals. One group received focused shockwave therapy (fSWT) using a device called ED1000, and the other group received radial wave therapy (rWT) using a Zimmer enPuls Pro device. Both treatments involved a series of short, painless sessions over several weeks. No anaesthesia or medication was required. Participants completed questionnaires on erectile function before treatment, after 3 months, and again after 1 year.

What are the possible benefits and risks of participating?
The possible benefit is improved erectile function and better sexual performance without the need for medication or surgery.
The treatment is considered safe and non-invasive, with no reported serious side effects. Some men might experience mild temporary discomfort during treatment, but no long-term risks are expected.

Where is the study run from?
1. Göksel Bayar Special Healthcare Company (Turkiye)
2. Ismail Basmaci Special Healthcare Company (Turkiye)

When is the study starting and how long is it expected to run for?
June 2021 to July 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Assoc. Prof. Göksel Bayar, goxelle@gmail.com, goksel.bayar@medicalpark.com.tr

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
20131113

Study information

Scientific Title
Comparative effectiveness of focused shockwave therapy and radial wave therapy for erectile dysfunction: a two-centre prospective cohort study

Study objectives
To evaluate the efficacy of focused and non-focused shock wave treatment of erectile dysfunction for at least 1 year.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/06/2023, Samsun University Local Ethics Committee (İstiklal Mahallesi Tekel Cad, Ballıca Kampüsü No:2, 19 Mayıs, Samsun, 55000, Türkiye; +90 (0)3623130055; samsununu.kaek@gmail.com), ref: 20231224

Study design
Non-randomized study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Erectile dysfunction

Interventions
This was a two-centre prospective cohort study, meaning men were treated and followed over time in two different hospitals. One group received focused shockwave therapy (fSWT) using a device called ED1000, and the other group received radial wave therapy (rWT) using a Zimmer enPuls Pro device. Both treatments involved a series of short, painless sessions over several weeks. No anaesthesia or medication was required. Participants completed questionnaires on erectile function before treatment, after 3 months, and again after 1 year. Chi-square and Student's t-tests will be used for statistical comparison. The Wilson test will be used to assess the effectiveness of the treatments themselves.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Shock wave treatment

Primary outcome(s)
Erectile function measured using the International Index of Erectile Function (IIEF) score before treatment, after 3 months, and after 1 year

Key secondary outcome(s))
Sexual function assessed using the Sexual Encounter Profile (SEP) before treatment, after 3 months, and after 1 year

Completion date
01/07/2024

Eligibility

Key inclusion criteria

Erectile dysfunction patients with vascular insuffiency

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
30 years

Upper age limit
70 years

Sex
Male

Total final enrolment
200

Key exclusion criteria
1. Pelvic surgery, e.g. radical prostatectomy
2. Radiotherapy
3. Neuropathic illness

Date of first enrolment
01/07/2023

Date of final enrolment
01/07/2024

Locations

Countries of recruitment
Türkiye

Study participating centre
Göksel Bayar Special Healthcare Company
Guzellller Mah Kavak Cad Medical Park Hastanesi
Gebze
Türkiye
41400

Study participating centre

Ismail Basmaci Special Healthcare Company
Artuklu Mah
Mardin
Türkiye
47060

Sponsor information

Organisation
Göksel Bayar Special Healthcare Company

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date