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The effect of Dr Allen's Device and Thermobalancing Therapy on erectile dysfunction in men with chronic prostate diseases

Submission date
17/12/2022

Recruitment status
No longer recruiting

Registration date
09/01/2023

Overall study status
Completed

Last Edited
20/05/2024

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) and benign prostate enlargement (BPE) – also known as an enlarged prostate or benign prostatic hyperplasia (BPH) – are common health conditions among men. The prevalence of histologically diagnosed BPE increases from 8% in men aged 40 years old to 40-50% in men aged 51 to 60 years old, to over 80% in men older than age 80 years. These health problems are often accompanied by erectile dysfunction (ED). It has been confirmed that novel thermobalancing therapy with Dr Allen's Device for Prostate Treatment reduces prostate inflammation in patients with CP/CPPS, decreases the size of benign prostate enlargement, and eases lower urinary tract symptoms (LUTS) associated with BPE. Also, this treatment has a positive effect on the health-related quality of life (HRQoL) in men with CP/CPPS and BPE. Moreover, no complications associated with the use of Dr Allen’s Device have ever been observed in patients with BPH and chronic prostatitis. Many studies show that commonly used medications and surgeries for CP/CPPS and BPE have a negative effect on the HRQoL, and lead to ED. Standard treatment options with drugs can cause side effects, especially in long-term use. Surgical interventions are associated with irreversible complications. Most of these side effects and complications affect erectile and sexual function causing emotional problems and depression. Solving these problems is, therefore, extremely important for men’s long-term health and well-being. Therefore, this study will evaluate thermobalancing therapy for ED and HRQoL in men with CP/CPPS and BPE. It is anticipated that Dr Allen’s Device and thermobalancing therapy will treat ED and improve erectile function, reduce the size of the inflamed or enlarged prostate gland, reduce urinary symptoms, and improve the quality of life in men with chronic prostatitis (CP/CPPS) or benign prostate enlargement (BPE). The findings may allow us to recommend this novel out-of-hospital treatment as a new safe solution for ED.

Who can participate?
Men aged between 40 and 55 years old with ED due to CP/CPPS or BPH

What does the study involve?
Thermobalancing therapy improves blood circulation in the affected prostate gland by means of local temperature regulation for a prolonged period of time. It is achieved with the continuous use of the wearable Dr Allen’s Device. Dr Allen’s Device for Prostate Treatment is designed as a soft belt with a thermoelement made from a special wax-based material. It maintains the required temperature when retained on the body; it needs to be placed correctly with the thermoelement covering the coccyx area of the back. A total of 100 participants will be recruited for the study: 50 participants will be placed in the treatment group and 50 participants will be placed in the control group. Every participant will be randomly assigned to either the treatment group or the control group. Thermobalancing therapy with Dr Allen’s Device will be used as a monotherapy. Patients in the treatment group will use Dr Allen’s Device. Patients in the control group will be under watchful waiting and will not receive treatment with Dr Allen’s Device. Every participant will be assessed 3 times during the study: before the start of the treatment, and 3 and 6 months after the start of the treatment.

What are the possible benefits and risks of participating?
The benefits of participating in this study include receiving a non-invasive and totally safe treatment with thermobalancing therapy and Dr Allen’s Device designed to improve erectile function and overall wellbeing in men with chronic prostatic diseases. Dr Allen’s Device provides an at-home treatment, without the need for hospitalisation or any other medical interventions. Dr Allen’s Device is easy to use and does not impede daily activities of its user. There are no risks associated with the use of Dr Allen’s Device, which is a Class 1 Medical Device.

Where is the study run from?
Fine Treatment (UK)

When is the study starting and how long is it expected to run for?
June 2022 to November 2023

Who is funding the study?
Fine Treatment (UK)

Who is the main contact?
Fine Treatment, info@finetreatment.com (UK)

Study website
https://finetreatment.com/

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CT-5-ED-TT-DAD

Study information

Scientific Title
Investigation of the effect of Thermobalancing therapy and Dr Allen's Device for Prostate Treatment on erectile dysfunction, prostate volume, and health-related quality of life in men with chronic prostatitis/chronic pelvic pain syndrome and benign prostate enlargement

Acronym

TT-DAD-ED-CP-BPE

Study objectives
The out-of-hospital treatment with Thermobalancing therapy and Dr Allen's Device for Prostate Treatment is expected to improve erectile function, reduce the size of the inflamed or enlarged prostate gland, reduce urinary symptoms, and improve health-related quality of life in men with chronic prostatitis/chronic pelvic pain syndrome and benign prostate enlargement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/07/2022, the Ethics Review Committee of the Government College University Faisalabad (Kotwali Road, Faisalabad, Punjab, 38000, Pakistan; +92(0)419200876; drmhrasool@gcuf.edu.pk), ref: GCUF/ERC/110

Study design
Single-centre prospective interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Treatment for erectile dysfunction in patients with benign prostate enlargement or chronic prostatitis/chronic pelvic pain syndrome

Interventions
The purpose of this clinical trial is to investigate the effect of the out-of-hospital treatment with Thermobalancing therapy and Dr Allen's Device for Prostate Treatment on erectile dysfunction, the size of the inflamed or enlarged prostate gland, urinary symptoms, and health-related quality of life (HRQoL) in men with ED linked to CP/CPPS or BPE.

Chronic prostatitis / chronic pelvic pain syndrome (CP/CPPS) and benign prostate enlargement (BPE) – also known as an enlarged prostate or benign prostatic hyperplasia (BPH) – are common health conditions among men. CP/CPPS affects 8.2% of men. The prevalence of histologically diagnosed BPE increases from 8% in men aged 40, to 40-50% in men aged 51 to 60, to over 80% in men older than age 80. These health problems are often accompanied by erectile dysfunction (ED).

It has been confirmed that novel Thermobalancing therapy and Dr Allen's Device for Prostate Treatment reduce prostate inflammation in patients with CP/CPPS, decrease the size of benign prostate enlargement, and ease lower urinary tract symptoms (LUTS) associated with BPE. Also, this treatment has a positive impact on the health-related quality of life in men with CP/CPPS and BPE. Moreover, no complications associated with the use of Dr Allen's Device have ever been observed in patients with BPH and chronic prostatitis.

Many studies show that commonly used medications and surgeries for CP/CPPS and BPE have a negative effect on the quality of life, and lead to ED. Standard treatment options with drugs can cause side effects, especially in long-term use. Surgical interventions are associated with irreversible complications. Most of these side effects and complications affect erectile and sexual function causing emotional problems and depression. Solving these problems is, therefore, extremely important for men's long-term health and well-being.

Therefore, new research on Thermobalancing therapy for ED and health-related quality of life in men with CP/CPPS and BPE is needed.

A total of 100 participants will be recruited for the study: 50 participants with ED due to CP /CPPS and 50 participants with ED due to BPH. Every participant in each of these 2 groups will be randomly assigned to either the treatment groups or the control groups in equal numbers of 25 participants in each group.

Thermobalancing therapy with Dr Allen's Device will be used as a monotherapy. Every participant in the treatment groups will be investigated during the clinical trial 3 times: before the start of the treatment, 3 and 6 months after the start of the treatment. Every participant in the control groups will be investigated during the clinical trial also 3 times: at the start of the observation period, 3 and 6 months later.

Patients in the treatment groups will use Dr Allen's Device. Patients in the control groups will be placed under watchful waiting and will not receive treatment with Dr Allen's Device. The data collected from the treatment groups will be compared to the control groups in watchful waiting. No other interventions, including medications and surgical procedures, will be used.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dr Allen's Device

Primary outcome measure
The following outcomes will be assessed three times in total, before, during and at the end of the treatment period:
1. Severity of erectile dysfunction measured using the International Index of Erectile Function (IIEF-5) Questionnaire
2. Volume of the prostate gland measured using ultrasound
3. Severity of urinary symptoms measured using the AUA Symptom Score Questionnaire

Secondary outcome measures

The following outcomes will be assessed three times in total, before, during and at the end of the treatment period:
1. Health-related quality of life (HRQoL) measured using the Short Form Survey Instrument (SF-36)
2. Serum levels of prostate-specific antigen, total testosterone, and 17β-estradiol (E2) measured using blood samples and standard techniques

Overall study start date
01/06/2022

Completion date
01/11/2023

Eligibility

Key inclusion criteria
Aged between 40 and 55 with ED due to CP/CPPS or BPH

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
The target sample size is 100 patients

Total final enrolment
100

Key exclusion criteria
1. Previous prostate surgeries
2. Infectious diseases
3. Severe comorbidities, such as cancer, heart failure, and end-stage chronic diseases
4. Cognitive impairment
5. Mental illness

Date of first enrolment
12/01/2023

Date of final enrolment
01/04/2023

Locations

Countries of recruitment
Pakistan

Study participating centre
Government College University Faisalabad
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Sponsor information

Organisation
Fine Treatment (United Kingdom)

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Industry

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Funder(s)

Funder type
Industry

Funder Name
Fine Treatment (United Kingdom)

Results and Publications

Publication and dissemination plan
1. Planned publication in a high-impact peer-reviewed journal
2. Presentations at medical conferences
Further information available at https://www.FineTreatment.com

Intention to publish date
01/05/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Simon Allen, Director, Fine Treatment, info@finetreatment.com.

• The type of data that will be shared: Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).
• Dates of availability: Beginning 9 months and ending 3 years following article publication.
• Whether consent from participants was required and obtained: Informed Consent will be obtained from all participants by signing the Informed Consent form before any trial specific procedures are performed.
• Comments on data anonymization: Data will be anonymised.
• Any ethical or legal restrictions: Data will be provided upon request for research purposes only.
• Any additional comments: Data will be made available to researchers who provide a methodologically sound proposal.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	01/06/2022	05/01/2023	No	No
Statistical Analysis Plan	version 1.0	01/06/2022	05/01/2023	No	No