Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of modulated extremely low frequency electromagnetic fields compared to placebo in the management of Chronic drug-resistant E. Coli-induced cystitis

Protocol summary

Study aim

To investigate the effectiveness of extremely low frequencies (ELF) electromagnetic fields in the treatment of drug-resistant E. Coli-induced chronic bacterial cystitis.

Design

Two-arm, parallel group, double blind randomized controlled clinical trial

Settings and conduct

The study will be conducted in ID MEDICALS Moretti Roma, Italy

Participants/Inclusion and exclusion criteria

Women, age 18 to 80 years, suffering from chronic E-coli indued drug-resistant cystitis will be recruited. Women with serious co-morbid conditions will be excluded.

Intervention groups

Experimental group: Experimental group will receive electromagnetic fields, modulated at extremely low frequencies . For treatment, a sequence of signals (BSB) will be created. In order to emit the BSB sequence, a PEMF ion resonance generator, Seqex (SISTEMI SRL) mod MED (compliant with Directive 93/42/EEC and standard EN 60601-1 regarding safety and essential performance, CE Certificate issued by Notified Body CE0051), will be used. This can write signal sequences, store them on a card, and emit them, emitting sequences from 1 to 80 Hz, with 30 waveforms, and signal intensity from 1 to 100 µT at the source. A total of 8 applications will be performed, twice a week with a 48-72 hour interval between each session (i.e., Monday and Thursday). Control group: The control group will receive placebo. Placebo will be used by placing the applicators without emitting signals, thus patients will have no idea whether they are in the experimental group or control group.

Main outcome variables

All participants will be tested for IL-6 and D-dimer (from a complete blood count), urine analysis (pH, specific gravity, urobilinogen, red blood cells, and leukocytes), and urine culture, detecting E. coli at levels greater than 100,000 CFU/ml.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211022052833N3**
Registration date: **2024-02-09, 1402/11/20**
Registration timing: **prospective**

Last update: **2024-02-09, 1402/11/20**
Update count: **0**

Registration date

2024-02-09, 1402/11/20

Registrant information

Name

Aatik Arsh

Name of organization / entity

Khyber Medical University

Country

Pakistan

Phone

+92 937 576111

Email address

aatikarsh@kmu.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-15, 1402/11/26

Expected recruitment end date

2024-05-15, 1403/02/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of modulated extremely low frequency electromagnetic fields compared to placebo in the management of Chronic drug-resistant E. Coli-induced cystitis

Public title

Electromagnetic fields for drug-resistant cystitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women, age 18 to 80 years, Women suffering from chronic E-coli indued drug-resistant cystitis. Chronic cystitis will be defined as at least 3 episodes of cystitis per year. The women with chronic cystitis will be labelled as drug-resistant if they have previously used six types of antibiotics (trimethoprim, nitrofurantoin, fluoroquinolones, sulfonamides, amoxicillin, and ampicillin) for at least 2 months without satisfactory clinical response.

Exclusion criteria:

History of myocardial infarction Stroke Uncontrolled diabetes Cancer Allergic skin reactions Any other condition that can affect participation in the trial

Age

From **18 years** old to **80 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **148**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization will be used in this study. Participants will distribute randomly into experimental (low frequencies electromagnetic field) and control (placebo) groups . This will be based on a computer-generated randomization schedule via open epi software (www.openepi.com) prepared before the study. Using software systems to define the intervention codes will dictate the group assignment for the participants.

Blinding (investigator's opinion)

Double blinded

Blinding description

The proposed clinical trial will be double-blind and patients and assessors will be blind. The control group will receive a placebo. Placebo will be used by placing the applicators without emitting signals, thus patients will have no idea whether they are in the experimental group or control group. Assessors who will collect data at baseline and post-treatment will not be aware of treatment allocation and thus will remain blind. The assessors will not be provided with randomization codes. The blinding will be broken once all participants and data have been completed (under normal circumstances). In an emergency, the researcher can define the intervention by calling the software system responsible for breaking the intervention code. The entire randomization code will be revealed when the study is completed, and the database is closed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Board, ID MEDICALS

Street address

2nd Floor, ID Medicals Building, Viale L. Moretti 12, 00163 Roma, Italy

City

Moretti

Postal code

00163

Approval date

2024-01-10, 1402/10/20

Ethics committee reference number

DIR/ID Medicals-EB/2401

Health conditions studied

1

Description of health condition studied

Chronic drug-resistant E. Coli cystitis

ICD-10 code

N30.1

ICD-10 code description

Interstitial cystitis (chronic)

Primary outcomes

1

Description

Detecting E. coli levels greater than 100,000 CFU/ml

Timepoint

Pre and post-treatment (1 month)

Method of measurement

Urine analysis and Urine culture: Urine analysis will be conducted using refractometric and cytofluorimetric

methods following SIBioC guidelines, and urine culture will be performed using a conventional method according to AMCLI and EUCAST guidelines.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Experimental group will receive electromagnetic fields, modulated at extremely low frequencies . For treatment, a sequence of signals (BSB) will be created. In order to emit the BSB sequence, a PEMF ion resonance generator, Seqex (SISTEMI SRL) mod MED (compliant with Directive 93/42/EEC and standard EN 60601-1 regarding safety and essential performance, CE Certificate issued by Notified Body CE0051), will be used. This can write signal sequences, store them on a card, and emit them, emitting sequences from 1 to 80 Hz, with 30 waveforms, and signal intensity from 1 to 100 µT at the source. A total of 8 applications will be performed, twice a week with a 48-72 hour interval between each session (i.e., Monday and Thursday).

Category

Treatment - Devices

2

Description

Control group: The control group will receive placebo. Placebo will be used by placing the applicators without emitting signals, thus patients will have no idea whether they are in the experimental group or control group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
ID MEDICALS

Full name of responsible person
Ivan D’Agostino

Street address
viale L. Moretti 12, 00163 Roma, ITALY

City
Moretti

Postal code
00163

Phone
+39 388 697 1279

Email
drivandagostino@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
CRESO S.r.l.

Full name of responsible person
Fabiola Marelli

Street address
CRESO S.r.l., via M. Masia 79, 22100 Como, ITALY.

City
Masia

Postal code
22100

Phone
+39 335 768 0033

Email
amministrazione@osteopatiacreso.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
CRESO S.r.l.

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
ID Medical

Full name of responsible person
Ivan D'Agostino

Position
Health specialist

Latest degree
Ph.D.

Other areas of specialty/work
Advanced Biophysical Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Data and documents

When the data will become available and for how long
After the trial completion, anonymized data will be available.

To whom data/document is available
Anonymized data will be available for researchers who show interest to further analyze or use the data.

Under which criteria data/document could be used
Trial manager will have the data/document available and he will share it upon a reasonable request.

From where data/document is obtainable
It can be obtained from Trial manager upon a reasonable request.

What processes are involved for a request to access data/document
Email to trial manager

Comments