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The impact of moxibustion on digestive system function and gut bacteria pattern in chronic kidney disease patients undergoing peritoneal dialysis

Submission date
07/04/2024

Recruitment status
No longer recruiting

Registration date
10/04/2024

Overall study status
Completed

Last Edited
09/04/2024

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Through extensive clinical experience, it has been demonstrated that blending traditional Chinese medicine with Western medical practices offers distinct benefits for treating chronic renal failure. This combination allows for mutual enhancement, yielding favorable outcomes such as alleviation of clinical symptoms, enhancement of renal function, and deceleration of renal failure progression. Our study aims to assess the effectiveness of incorporating moxibustion alongside peritoneal dialysis (PD) in treating patients diagnosed with chronic renal failure (CRF).

Who can participate?
Patients aged 18 years or older with chronic renal failure receiving moxibustion combined with peritoneal dialysis

What does the study involve?
We studied patients diagnosed with chronic kidney failure (CRF) who underwent moxibustion in conjunction with peritoneal dialysis (PD) at our hospital (referred to as the moxibustion group), alongside patients also diagnosed with CRF who solely underwent PD (referred to as the control group).

What are the possible benefits and risks of participating?
Benefits:
1. Gain access to novel treatment options.
2. Alleviate financial strain.
3. Enhance understanding of the latest developments regarding your condition.
4. Receive increased attention from medical professionals.
5. Access high-quality medical care.

Risks:
1. Requires additional energy expenditure.
2. Possibility of ineffective treatment.

Where is the study run from?
Jinshan Branch of the Sixth People's Hospital (China)

When is the study starting and how long is it expected to run for?
March 2020 to March 2023

Who is funding the study?
Jinshan Branch of the Sixth People's Hospital (China)

Who is the main contact?
LiuKun, saynever2004@126.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
20240407

Study information

Scientific Title
Study on clinical effect and mechanism of moxibustion therapy in improving gastrointestinal dysfunction in uremia peritoneal dialysis

Study objectives
Moxibustion combined with peritoneal dialysis (PD) can regulate the structure of the gut microbiota to improve renal and gastrointestinal functions in chronic renal failure (CRF) patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/12/2020, Shanghai Sixth People's Hospital Jinshan Branch Medical Ethics Management Committee (Jinshan Branch of the Sixth People's Hospital, No.147 Health Road, Zhujing Town, Jinshan District, Shanghai, 201599, China; +86 21 5731 0206; lunli2020@126.com), ref: jszxyy202007

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic kidney disease peritoneal dialysis patients

Interventions
From March 2020 to February 2022, 52 patients with chronic kidney failure (CRF) who received moxibustion combined with peritoneal dialysis (PD) in our hospital (moxibustion group) and 50 patients with CRF who only received PD (control group) will be studied to observe the effects of moxibustion on gastrointestinal function and intestinal microbial structure in peritoneal dialysis patients with chronic kidney disease

Moxibustion group: Moxibustion treatment was performed during PD, along with conventional Western medicine treatments, such as improving anemia and controlling blood sugar.

Control group: only PD and western medicine conventional treatment.

Both groups were given appropriate diet and gastrointestinal management, and the entire study period lasted 12 weeks.

Intervention Type
Mixed

Primary outcome(s)
1. After 12 weeks of treatment, gastrointestinal function was analyzed by blood tests of secretion of gastrin, motilin, cholecystokinin, somatostatin and growth hormone releasing peptide before and after treatment.
2. Fecal samples were collected 12 weeks after treatment for 16S rDNA analysis to observe changes in fecal microbial characteristics

Key secondary outcome(s))
Renal function index: After 12 weeks of treatment, Blood routine markers and blood electrolytes were detected by blood. Routine biochemical parameters and 24-hour urinary protein quantification (UPQ) by urine testing

Completion date
01/03/2023

Eligibility

Key inclusion criteria
1. Aged > 18 years old;
2. Clinical diagnosis of CRF with specific indications for PD.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
71 years

Sex
All

Total final enrolment
102

Key exclusion criteria
1. Decreased peritoneal clearance rate caused by various abdominal lesions;
2. Within 3 days of abdominal surgery and no complete healing of the wound, which could easily lead to dialysate leaks;
3. Localized inflammatory lesions in the peritoneum, which could be spread by PD;
4. Late pregnancy or large intra-abdominal tumors, which could result in reduced abdominal volume and subsequent unsatisfactory effect of PD;
5. Extensive abdominal wall infection or severe burns, which could cause failure of intubation;
6. Intra-abdominal vascular diseases, such as polyangiitis, severe arteriosclerosis, scleroderma, which could reduce the dialysis efficacy;
7. Severe respiratory insufficiency; in such patients, excessive fluid intake would aggravate respiratory insufficiency, and if the patients were still required to receive PD, fluid intake was less;
8. Long-term insufficiency of protein and caloric intake; such patients were not suitable for PD because PD could lead to daily loss of protein more than 6 g

Date of first enrolment
01/03/2020

Date of final enrolment

28/02/2022

Locations

Countries of recruitment
China

Study participating centre
Shanghai Sixth People's Hospital Jinshan Branch
Jinshan Branch of the Sixth People's Hospital, No.147 Health Road, Zhujing Town, Jinshan District
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China
201599

Sponsor information

Organisation
Shanghai Sixth People's Hospital Jinshan Branch

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Shanghai Sixth People's Hospital Jinshan Branch

Results and Publications

Individual participant data (IPD) sharing plan
Please use contact details to request raw data (LiuKun,saynever2004@126.com)

IPD sharing plan summary
Available on request