ISRCTN66069359 https://doi.org/10.1186/ISRCTN66069359

Observation of the effects of predictive nursing in patients with HIV/AIDS undergoing anal fistula surgery

Submission date
24/10/2024

Recruitment status
No longer recruiting

Registration date
06/11/2024

Overall study status
Completed

Last Edited
05/11/2024

Condition category
Other

[_] 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
Constipation caused by fear of defecation is a common complication of anal fistula surgery. HIV infection is common in patients with a variety of anorectal diseases, postoperative prognosis is poorer, and complication rates are relatively high. Predictive nursing, as one of the new clinical nursing models, can achieve the purpose of reducing postoperative complications by the comprehensive evaluation of patients by medical staff.

Who can participate?
Patients with HIV/AIDS aged 18 years and older undergoing surgical treatment of complex anal fistula.

What does the study involve?
The patients were randomly assigned to two groups. No patients had acute symptoms on presentation, and all underwent a series of standardised clinical assessments, including ultrasound, digital rectal examination and colonoscopy, to confirm the absence of contraindications to the surgical procedures used in this study; the types of surgery included cutting or non-cutting seton, ligation of the intersphincteric fistula tract, anorectal advancement flap, fibrin glue injection, stem cell treatment and laser treatment. After admission, patients in the control group received routine nursing, and those in the intervention group received predictive nursing based on routine nursing.

What are the possible benefits and risks of participating?
The ability of patients to care for themselves may improve, and the incidence of postoperative constipation may decrease. There are no direct risks to participants.

Where is the study run from?
Beijing Youan Hospital, Capital Medical University (China)

When is the study starting and how long is it expected to run for?
January 2021 to January 2023

Who is funding the study?
1. Beijing Hospitals Authority Youth Programme
2. Beijing You'an Hospital affiliated with Capital Medical University, 2021 Hospital Young and Middle-aged Talents Incubation Project (China).

Who is the main contact?
Li-Li Zhang, zzhanglili@yeah.net

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Observation of the effects of predictive nursing on postoperative constipation prevention and self-care ability in patients with HIV/AIDS undergoing anal fistula surgery

Study objectives

To explore the effects of predictive nursing on the prevention of postoperative constipation and self-care ability in patients with HIV/AIDS undergoing anal fistula surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/12/2021, Ethics Committee of Beijing Youan Hospital, Capital Medical University (No.8, Xi Tou Tiao, Youanmen wai, Fengtai District, Beijing, 100069, China; +86 010-83997028; youanyuanban@163.com), ref: LL-2021-160-K

Study design
Randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Laboratory, Medical and other records, Telephone

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Constipation prevention, self-care ability

Interventions
The patients were randomly assigned to two groups using block randomisation, with 100 patients in each group. The experimental group received predictive nursing based on routine nursing, which includes: risk assessment, diet care, psychological care, bowel care, and anal function exercise. Whereas the control group received routine nursing, including perioperative routine health education guidance.

Control group: routine nursing.
The whole intervention period lasted for 7 days. The main contents are perioperative routine health education guidance, including preoperative, intraoperative and postoperative health education guidance, psychological nursing, and medication nursing. These measures were designed to assist patients in handling psychological stress and emotional issues, thereby enhancing treatment compliance.

Experimental group: predictive nursing based on routine nursing.
The experimental group received predictive nursing based on routine nursing, which includes: risk assessment, diet care, psychological care, bowel care, and anal function exercise. The intervention period was 7 days.

Follow-up time point: The follow-up was performed on the 7th day after discharge. Follow-up included an assessment of the patient's constipation. For patients with constipation, the focus was on whether there is still constipation to check the recovery of the surgical site for complications, such as infection and adhesion. At the same time, the patients were asked about their quality of life and psychological status at each follow-up visit to understand the impact of the treatment on their overall life.

Follow-up: Outpatient review, telephone interview and online questionnaire were used to ensure a comprehensive collection of patient information.

Intervention Type
Behavioural

Primary outcome measure
1. The effectiveness of constipation prevention was measured using outpatient review, telephone interview and online questionnaire before and after the intervention, according to the Consensus on Traditional Chinese Medicine Diagnosis and Treatment of Constipation (2017) as follows: 1) ineffective: bowel movements less than 3 times per week with hard stools, difficult defaecation or a feeling of incomplete evacuation; 2) effective: bowel movements more than once within 3 days; and 3) highly effective: bowel movements more than once within 2 days. The effective rate of constipation prevention (%) was calculated by dividing the sum of highly effective and effective cases by the total number of cases and multiplying by 100.
2. Self-care ability measured using the Exercise of Self-Care Agency (ESCA) scale before and after the intervention

Secondary outcome measures
The following secondary outcome measures are assessed using data recorded in patient medical records:
1. Preoperative history of constipation measured by asking the patient whether he has had constipation in the past month before surgery
2. Anal fistula duration
3. Operative time
4. Blood loss
5. Type of surgery
6. CD4 cell counts / viral loads measured using standard laboratory methods and a preoperative blood test
7. Bowel disorders and type of anal fistula

Overall study start date
01/01/2021

Completion date
31/01/2023

Eligibility

Key inclusion criteria
1. A confirmed HIV infection / AIDS diagnosis according to the 2021 edition of the Chinese Guidelines for the Diagnosis and Treatment of HIV/AIDS, having received antiretroviral therapy and with a current CD4+ T-cell count of ≥200 cells/μL

2. Aged ≥18 years
3. Ability to cooperate with the researchers and complete the study-related procedures and data collection
4. Voluntary participation in the study and signing of an informed consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Total final enrolment
200

Key exclusion criteria
1. Presence of other anal or colorectal diseases, such as perianal dermatitis or colorectal tumours
2. Recurrent transsphincteric anal fistula
3. Presence of severe diseases such as cardiac, hepatic or renal conditions
4. History of previous anal surgery
5. Presence of mental or psychological disorders

Date of first enrolment
01/01/2022

Date of final enrolment
31/01/2023

Locations

Countries of recruitment
China

Study participating centre
Beijing Youan Hospital, Capital Medical University
No.8, Xi Tou Tiao, Youanmen wai, Fengtai District
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Sponsor information

Organisation
Beijing YouAn Hospital

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Sponsor type
Hospital/treatment centre

Website
https://www.bjyah.com/

ROR
https://ror.org/04etaja30

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Beijing Hospitals Authority Youth Programme

Funder Name
Beijing You'an Hospital affiliated to Capital Medical University, 2021 Hospital Young and middle-aged Talents Incubation Project

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Li-Li Zhang, Email: zzhanglili@yeah.net

IPD sharing plan summary

Available on request