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Research article

# Clinical efficacy of the bared external anal sphincter (BEAS) in high horseshoe-shaped anal fistulas: Protocol for a real-world, prospective cohort study

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ABSTRACT

*Background:* High horseshoe-shaped anal fistula (HHAF) is a complex disease that manifests in the perianal region and typically requires surgical intervention for treatment. However, the current therapeutic approaches are limited by the high rates of postoperative recurrence and anal incontinence. To overcome the limitations of traditional surgical approaches, we introduce the bared external anal sphincter (BEAS) technique. Our study aims to compare the clinical efficacy of BEAS surgery with that of the modified Hanley procedure in a real-world setting.

*Materials and methods:* This single-centre, prospective cohort study will be conducted in a tertiary hospital in China and aims to evaluate the short-term clinical efficacy and safety of BEAS surgery and modified Hanley surgery in HHAF patients from March 2024 to March 2026. Data from the prospective database of this tertiary referral hospital will be used to obtain insights into the clinical outcomes of these surgical treatments. The primary outcome of this study will be the wound healing rate within six months, while the secondary outcomes will include the time to return to work, the maximum visual analogue scale pain score (VAS-PS) within 1–5 days postsurgery, and the Cleveland Clinic Florida Incontinence Score (CCF-IS) and Quality of Life in Anal Fistula Questionnaire Score (QoLAF-QS) at 1, 3, and 6 months postsurgery. Moreover, logistic regression analysis will be used to explore the risk factors for anal fistula recurrence after the BEAS procedure.

*Discussion:* This will be the first cohort study to evaluate the differences in therapeutic outcomes between patients who undergo BEAS surgery and patients who undergo surgery via the modified Hanley procedure. By conducting a detailed observation of the efficacy and treatment results of

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these two surgical methods, this study aims to reveal the differences the clinical effectiveness of these approaches and to provide evidence-based support for future randomized controlled trials (RCTs).

## Trial registration number

ChiCTR2300078165.

## 1. Introduction

An anal fistula is defined as a pathological canal that forms between the anal canal or rectum and the skin surrounding the anus; from a clinical perspective, anal fistulas primarily present with recurrent purulent discharge, pain, and itching in the affected area [1]. Epidemiological data indicate that the incidence rate of anal fistulas is approximately 8.6 cases per 100,000 individuals [2]. As one of the refractory and complex anal fistulas, high horseshoe-shaped anal fistula (HHAF) typically refers to fistulous tracts located deep in the posterior aspect of the anus. Its occurrence is often associated with the spread of abscesses within intersphincteric spaces, with the deep postanal space (DPAS) and deep postanal intersphincteric space (DPIS) being the most commonly affected spaces [3–6]. As the anal fistula progresses, the tract can extend to involve the ischiorectal fossa, presenting as unilateral or bilateral horse-shoe shaped extensions [7–9]. The complexity of the anatomical location of HHAFs and their relationship with surrounding structures render treatment more challenging, thereby imposing greater demands on the selection of treatment strategies [10]. Consequently, there is an urgent need to explore and establish more effective and safer surgical strategies. The Hanley procedure is widely acknowledged as an effective surgical method for treating horseshoe anal fistulas. The original Hanley procedure primarily involves incising the complex sphincter muscle posteriorly, while the modified Hanley procedure utilizes cutting setons for delayed fistulotomy [9–11]. However, the longitudinal incision technique employed in this surgery may compromise the integrity of the external anal sphincter, potentially adversely affecting the patient's anal function. In addition to sphincter damage, difficulties in establishing proper drainage pathways for the primary lesion during surgery, the distance of the primary lesion from the skin surface, and the narrowness of the posterior midline incision may lead to disease recurrence and urinary incontinence issues [11,12].

Due to the limited variety of treatment options available for HHAFs and the lack of uniformity in surgical standards within the industry, the current surgical approaches fail to adequately meet the needs of patients in terms of both cure rates and safety. In recent years, various minimally invasive procedures have been studied and applied in the treatment of fistulas, such as fibrin glue injection [13], anal fistula plugs [14], photodynamic therapy [15], transanal opening of the intersphincteric space [16], endorectal advancement flaps [17], ligation of the intersphincteric fistula tract [18], video-assisted anal fistula treatment [19], and fistula-tract laser closure [20]. However, the treatment outcomes for HHAFs are still somewhat unsatisfactory. In the medical community, it is widely acknowledged that precise management of the internal opening and ensuring adequate drainage are fundamental principles in the treatment of fistulas [21,22].

The bare external anal sphincter (BEAS) technique, has been previously reported as a novel surgical technique [6]. This technique involves an intersphincteric and an extrasphincteric surgical approach to fully expose and drain the two crucial spaces involved in the formation of HHAFs. Additionally, closure of the internal opening is achieved through the advancement of the musculomucosal flap and the external anal sphincter (EAS). The main advantage of the BEAS procedure lies in preserving the function of the anal sphincter and maintaining the normal anatomical structure while ensuring adequate drainage of the two important abscess spaces. This enables patients to recover from normal life earlier and reduces pain. The current accumulation of clinical cases and advancements in BEAS surgery in China have led to the recognition of relevant results by peers [6,23]. However, no study has compared the efficacy of BEAS with that of other surgical methods in real clinical settings; thus, its clinical advantages remain unknown. Observational studies reflect real-world situations and serve as practical methods to analyse the effectiveness and safety of BEAS surgery compared to classic surgery for HHAF. Additionally, these findings will provide valuable information for clinical practice in HHAF treatment and serve as a basis for assessing the exact efficacy of BEAS in subsequent randomized controlled trials (RCTs). Therefore, we designed this prospective real-world cohort study to evaluate the clinical effectiveness of the BEAS procedure. The primary outcome of this study is the wound healing rate within six months. Secondary outcomes include time to return to work, maximum visual analogue scale (VAS) pain score within 1–5 days post-surgery, and the Cleveland Clinic Florida Incontinence Score (CCF-IS) and Quality of Life in Anal Fistula Questionnaire Score (QoLAF-QS) at 1, 3, and 6 months post-surgery.

## 2. Patients and methods

### 2.1. Study design

This study will use a single-centre prospective cohort design. The data will be extracted from a tertiary referral hospital's prospective database. We will rigorously screen patients with HHAF, including those who meet predefined inclusion and exclusion criteria and who have undergone one of the two different surgical treatment methods. Based on the surgical treatment received, patients will be divided into two groups: the BEAS group and the modified Hanley group. All participants have provided signed informed consent prior to participating. The design and implementation of this study will strictly adhere to the guidelines of the Helsinki Declaration

[24], ensuring that all research activities comply with internationally recognized ethical standards. This study protocol has been approved by the ethics committee of the local tertiary referral hospital (Approval Number: 2023-1382-149-01) and has been registered with the Chinese Clinical Trial Registry (Registration Number: ChiCTR2300078165). This study will be reported in accordance with the STROCSS criteria [25]. The anticipated implementation period of the study is from March 2024 to March 2026.

### 2.2. Participants

This study will enrol patients aged between 18 and 65 years who have been diagnosed with HHAF through magnetic resonance imaging (MRI) (Fig. 1a and b) and intraoperative examination under anaesthesia, patients exhibiting lesions involving at least one-third of the anal sphincter complex, and patients who have undergone either BEAS surgery or modified Hanley surgery. Patients with mild anal fistulas, patients who have been diagnosed with Crohn's disease, patients who are undergoing cancer treatment, patients with infections (such as sepsis, tuberculosis, or HIV), patients with autoimmune diseases, patients who are lactating or pregnant, or patients who are receiving long-term steroid treatment or corticosteroid therapy will be excluded from the study.

During the preoperative phase, it is imperative for physicians to meticulously assess the patient's unique condition and personal preferences to select the most appropriate surgical procedure. This decision must be made in consultation with the patient, ensuring mutual understanding and agreement. The development of the treatment plan necessitates thorough communication and collaborative discussion between the patient and surgical experts who are unaffected by any constraints or interventions introduced by this study. Following the surgical procedure, essential patient details and surgical outcomes will be systematically integrated into the hospital's database for subsequent analytical and research purposes.

### 2.3. Surgical technique

#### 2.3.1. Modified Hanley procedure

The modified Hanley technique [26] is based on the fact that the primary fistula opening is usually located in the posterior midline crypt. During the operation, a posterior midline incision will be extended from the subcutaneous external sphincter to the coccyx, dividing the superficial external sphincter muscle in half and entering DPAS (Fig. 2a). A probe will be removed through the drainage incision after being placed through the primary opening in the posterior midline crypt. With a silk ligature, a pure rubber band will be connected to the probe and removed through the sphincter fistulous tract. The band will be loosely secured around the subcutaneous external sphincter, the lower half of the internal sphincter, and the conjoined longitudinal muscle (Fig. 2b). In the acute phase of the disease, in addition to drainage of the retroanal space, a bilateral paraanal incision will be made on the posterior ischiorectal space to facilitate drainage of the lower lateral extension of the levator ani muscle. Then, the wound will be stuffed with fine gauze and drained for 2 days. After the operation, the cotton block and gauze will be bandaged under pressure and fixed with adhesive tape.

When the abscess cavity involves the DPIS, the treatment for acute supralevator anorectal abscesses involves performing a complete internal sphincterotomy. Additionally, the index finger is inserted through the ruptured longitudinal muscle site into the abscess cavity to guarantee effective drainage of the significant amount of pus present. This manual manipulation not only verifies the location and extent of the abscess but also aids in the enlargement of the perforation site of the longitudinal muscle and the evacuation of pus, which is a vital step in preventing further infection and promoting healing.

#### 2.3.2. BEAS procedure

- **Intersphincteric approach (IS approach)** First, the intersphincteric groove will be passed through to determine the internal and external anal sphincters, and an arc-shaped incision will be made along the intersphincteric groove directly behind the anal canal (IS approach). Then, an electrical scalpel will be used to carefully separate the internal anal sphincter (IAS) and the EAS gap towards the head until it stops at 0.5 cm above the corresponding position of the internal opening (Figs. 3a–4a and 5a).
- **Lateral-external-sphincteric approach (LES approach)** On the rear side of the anal canal, a curvilinear incision will be made along the edge of the EAS to expose the free EAS (LES approach). Under the traction of a self-retaining retractor (Lone Star, Cooper

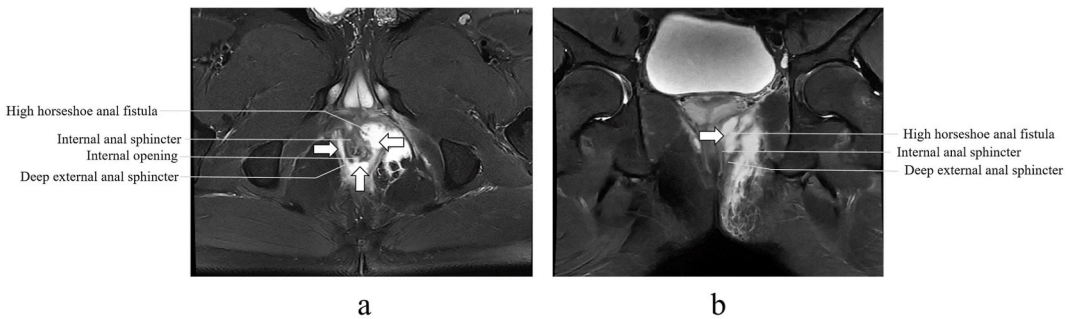


**Fig. 1.** The diagrams of preoperative MRI. (a) The cross-section of the perianal structure. **(b)** Pelvic coronal section of the perianal structure.

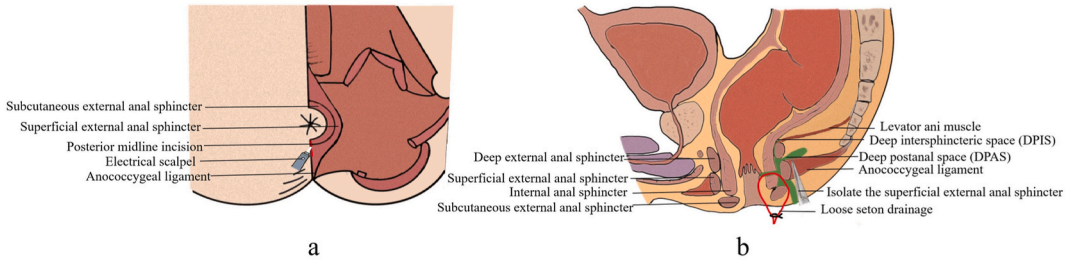


**Fig. 2.** Modified Hanley procedure. **(a)** View of the outside appearance. **(b)** Sagittal section of the pelvis.

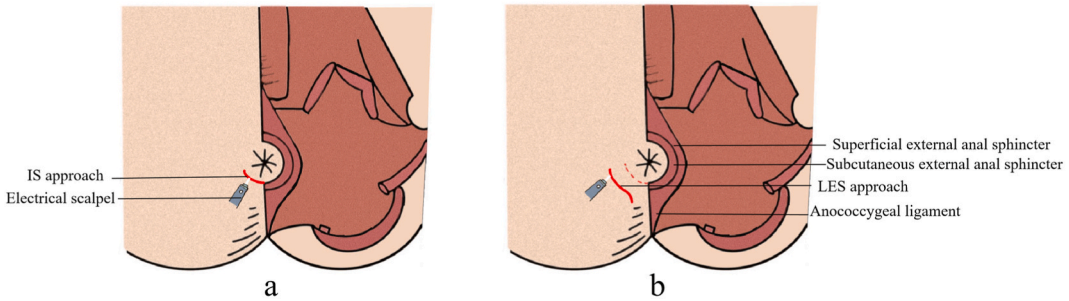


**Fig. 3.** BEAS procedure. View of the outside appearance. **(a)** Intersphincteric approach (IS approach). **(b)** Lateral-external-sphincteric approach (LES approach).

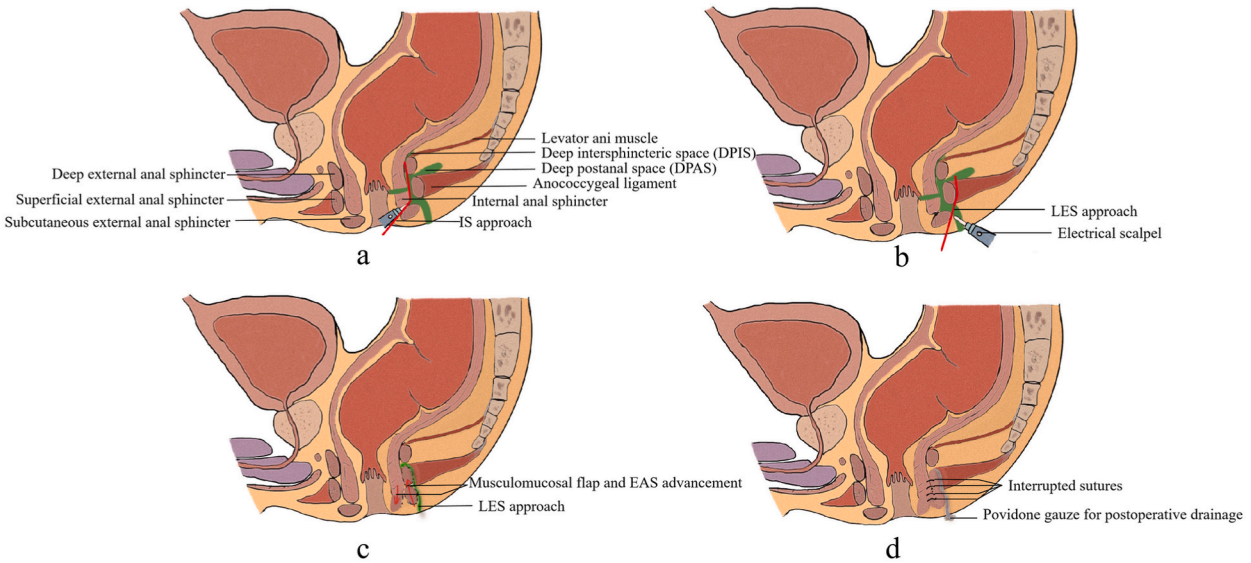


**Fig. 4.** BEAS procedure. Sagittal section of the pelvis. **(a)** Intersphincteric approach (IS approach). **(b)** Lateral-external-sphincteric approach (LES approach). **(c)** Musculomucosal flap and EAS advancement. **(d)** LES approach is kept open and stuff it with povidone gauze for post-operative drainage.

Surgical, Trumbull, CT), the electrical scalpel will be used to dissociate along the outer edge of the EAS to the head end until reaching the deep part of the EAS (Figs. 3b–4b and 5b).

- **Exposure of DPIS** Through the IS approach, a combination of sharp and blunt dissection techniques will be utilized to progressively separate the IAS from the EAS bilaterally along the intersphincteric plane. This separation will continue until the presence of an abscess or fistula deep within the EAS is identified by the surgeon. The dissection will then be extended cephalad, thus ensuring comprehensive exposure of the medial surfaces of both the DPIS and the EAS (Fig. 5c).

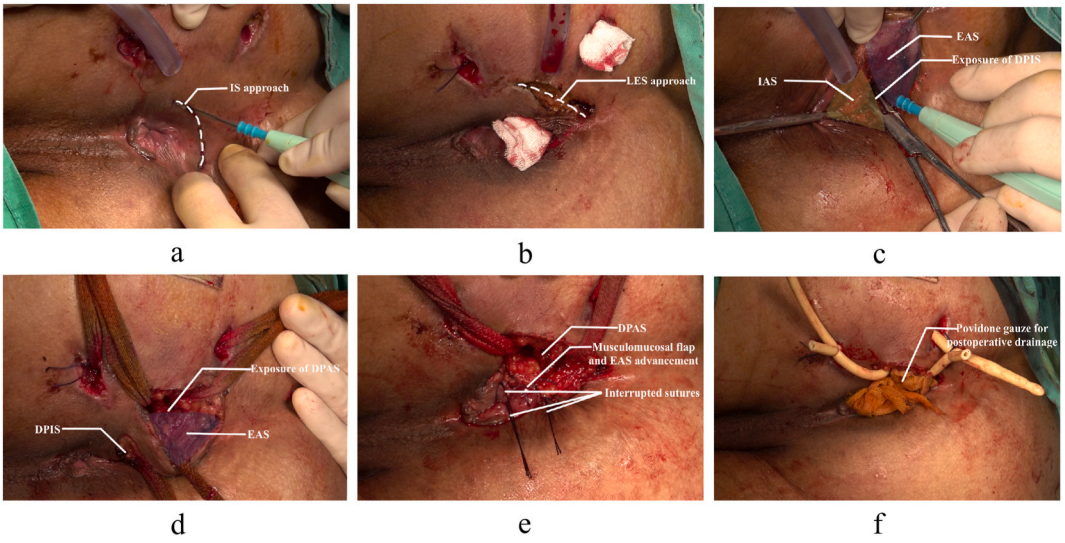


**Fig. 5.** Diagram of BEAS Surgical Procedure Steps. (a) IS approach. **(b)** LES approach. The dissection of LES approach is along the outer edge of the EAS to bare the EAS. **(c)** Exposure of DPIS. **(d)** Exposure of DPAS. Expose DPIS and DPAS to reach the fistula through IS approach and LES approach, respectively. **(e)** Musculomucosal Flap and EAS Advancement. Advance the musculomucosal flap and the EAS to ensure that the internal opening can reach the lower edge of the EAS without tension. Subsequently, close the intersphincteric incision (IS approach) using interrupted sutures while maintaining the LES approach. **(f)** Visual field after suture. IS=Intersphincteric; LES=Lateral-external-sphincteric; EAS = external anal sphincter; DPIS = deep intersphincteric space; DPAS = deep postanal space.

- **Exposure of the DPAS** With the help of a self-retaining retractor, the electric scalpel will be used to continue to dissociate to the cephalic end along the LES to fully expose the DPAS until the two approaches of the IS approach and LES approach converge at the top of the EAS (or the top of the HHAF abscess cavity) (Fig. 5d).

**Table 1**
Timetable of study.

| TIMEPOINT | Enrolment | 1-5 days | 1 month | 3 months | 6 months |
|---|---|---|---|---|---|
| **ENROLLMENT** | | | | | |
| Characteristics* | × | | | | |
| Operation time | × | | | | |
| Intraoperative blood loss | × | | | | |
| **ASSESSMENTS** | | | | | |
| Clinical cure rate | | | | | × |
| The time back to work | | | ← | — | → |
| VAS-PS | | × | | | |
| QoLAF-QS | | | × | × | × |
| CCF-IS | | | × | × | × |
| Safety Outcomes | ← | — | — | — | → |

* More details are shown in Table 2.

- **Musculomucosal flap and EAS advancement** After repeatedly irrigating the DPIS, DPAS and abscess cavity with povidone and hydrogen peroxide, the bare EAS will be pushed to the head, and the internal opening on the musculomucosal flap will be confirmed to reach the inferior edge of the EAS without tension. The IS approach will be closed with interrupted sutures using 2-0 Vicryl synthetic absorbable surgical sutures (Coated VICRYL, 2–0, ETHICON Inc., China). The LES approach will be kept open, and povidone gauze will be used for postoperative drainage. The wound will be observed for active bleeding, and the pathological tissue will be sent for examination. After the operation, cotton blocks and gauze will be used to cover the wound, which will then be fixed with wide adhesive tape (Fig. 4c and d and Fig. 5e and f).

### 2.4. Statistical analysis

Data processing and statistical analyses will be performed using SPSS Statistics 25.0 (IBM Inc., IL, USA) software and R software (version: 4.3.2). Continuous variables, such as age, BMI, operation time, intraoperative blood loss, and maximum pain score 1–5 days after the operation, will be expressed as the mean ± standard deviation and compared between groups using the independent samples *t*-test if they are normally distributed and exhibit homogeneity of variance. Otherwise, the data will be presented as medians, and the Mann–Whitney *U* test will be used for statistical analysis. Categorical variables such as sex, previous fistula surgery, comorbidities, park classification, horseshoe anal fistula type, internal opening location, and space involved will be expressed as numbers and percentages and compared using the chi-square test or Fisher's exact test. Efficacy indicators that require repeated measurements, such as CCF-IS and QoLAF-QS scores, will be analysed using repeated-measures ANOVA and a repeated-measures mixed effects model. Risk factors with a univariate association of $P < 0.1$ will be eligible for inclusion in the multivariate logistic regression model, and the results will be expressed as odds ratios (OR) and 95 % confidence intervals (CIs). $P < 0.05$ will indicate statistical significance, and all statistical tests will be bilateral. Due to the potential importance of clinically relevant factors identified in clinical reports, even if $P > 0.1$, it is recommended that these factors be included in the regression equation for adjustment.

The confounders were chosen based upon our previous studies [6,23]. These variables include patient baseline data (age, BMI, gender, previous fistula surgery, comorbidities, park classification, type of horseshoe anal fistula, location of internal opening, space involved, duration of disease, Antibiotic usage), operative time and intraoperative blood loss. The specific follow-up timepoints and assessments are shown in Table 1. The baseline data collected are shown in Table 2. All confounding variables listed above will be used as adjustment variables in the recurrence analysis to control for confounding factors in the comparison of fistula operations.

**Table 2**
Comparison of baseline characteristics between patients undergoing BEAS and modified Hanley.

| Variable | Overall cohort | | |
|---|---|---|---|
| | BEAS | modified Hanley | *P* value |
| Age, y (mean ± SD) | × | × | × |
| BMI, kg/m$^2$(mean ± SD) | × | × | × |
| Gender, n (%) | | | × |
| Male | × | × | |
| Female | × | × | |
| Previous fistula surgery, n (%) | | | × |
| Yes | × | × | |
| No | × | × | |
| Duration of disease | × | × | × |
| Antibiotic usage | | | |
| Yes | × | × | × |
| No | × | × | |
| Comorbidities, n (%) | | | × |
| None | × | × | |
| Diabetes mellitus | × | × | |
| Hypertension | × | × | |
| Other pathology | × | × | |
| Parks classification, n (%) | | | × |
| Suprasphincter fistula | × | × | |
| Extrasphincter fistula | × | × | |
| High intersphincteric fistula | × | × | |
| Types of horseshoe anal fistula, n (%) | | | × |
| Circular | × | × | |
| Anterior | × | × | |
| Posterior | × | × | |
| Location of internal opening, n (%) | | | × |
| Anterior | × | × | |
| Posterior | × | × | |
| Space involved, n (%) | | | |
| DPIS | × | × | × |
| DPAS | × | × | |
| DPIS and DPAS | × | × | |

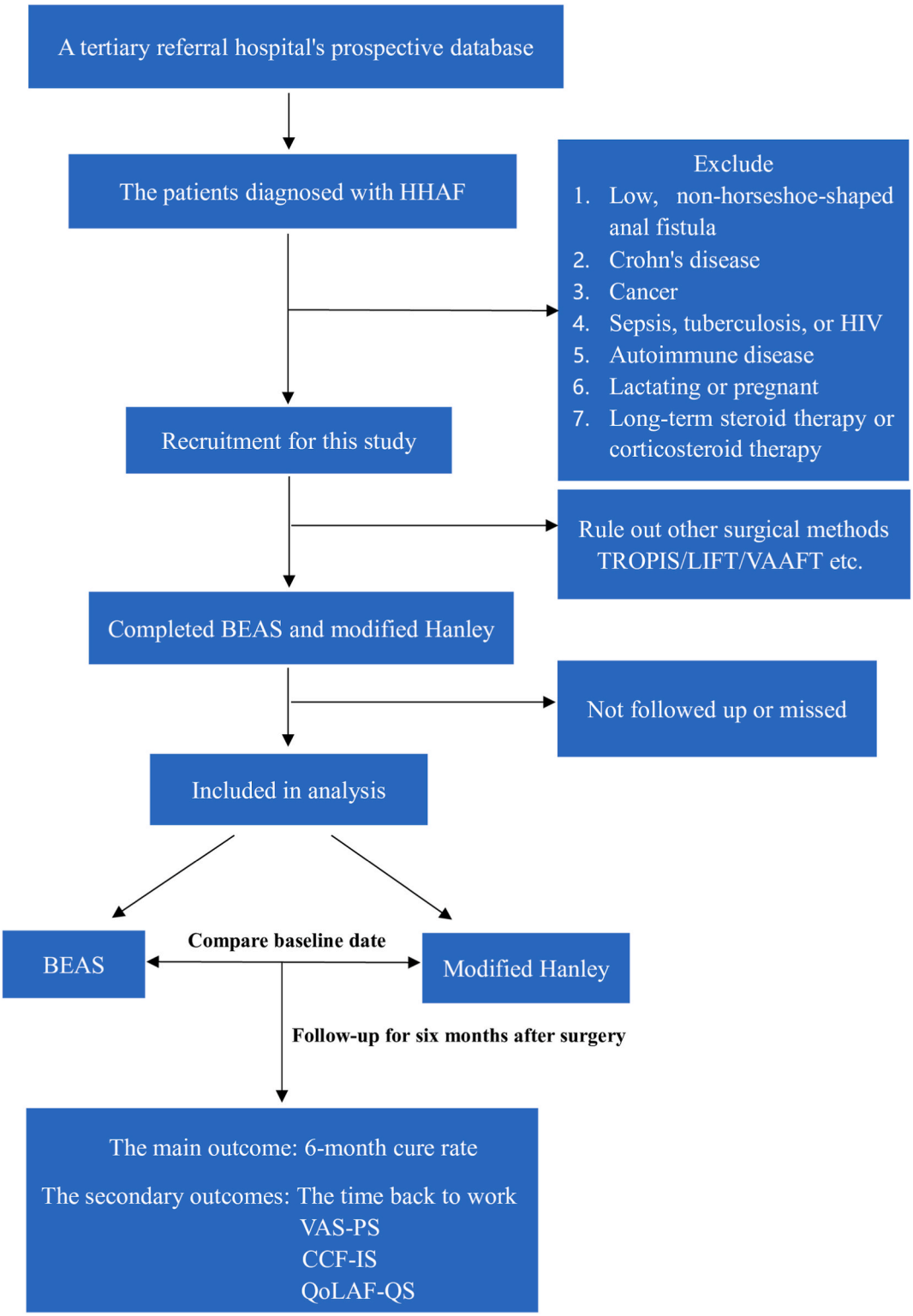


**Fig. 6.** Study process: flowchart of the study procedure.

### 2.5. Sample size calculation

The minimum sample size will be calculated using PASS15 software (NCSS, USA). The purpose of the power calculation in this prospective cohort study is to ensure that the sample size is sufficient to detect a statistically significant difference in the primary outcome (wound healing rate within six months) between the BEAS and modified Hanley surgical groups. The expected healing rates are based on previous clinical observations and literature, with an anticipated healing rate of 93.75 % [6] for the BEAS procedure and 73 % [27–29]for the modified Hanley procedure. Assuming $\alpha = 0.05$ and $1\text{-}\beta = 0.8$, the minimum required sample size was calculated to be 47 patients per group. To account for potential dropouts and loss to follow-up, this number was increased by 10 %, resulting in a target recruitment of at least 53 patients per group. The flow of our study is shown in Fig. 6.

### 2.6. Data collection and quality management

We will screen patients with HHAF who have undergone BEAS surgery or modified Hanley surgery from the hospital database and recorded their demographic characteristics and baseline information related to the surgery. All the data will be entered into a Microsoft Excel dataset for future analysis. Access to the study data will be restricted to only the members of our study team and the ethics committee. Random data checks will be performed during data extraction and data entry to prevent errors, missing or out-of-range values, and logical inconsistencies.

## 3. Clinical outcomes

### 3.1. Primary outcome

Patients will undergo a follow-up observation period lasting at least six months. During this period, the progress of the healing process will be documented, specifically focusing on the six-month postoperative stage. For the purposes of this study, healing is deemed complete when all symptoms and signs related to anal fistulas have resolved, encompassing the complete healing of the wound extending from the sphincter to the external opening. Additionally, the absence of infection at the surgical site and the formation of perianal abscesses are crucial criteria. Furthermore, disease recurrence is defined as the persistence or reappearance of symptoms within six months postsurgery [22,30].

### 3.2. Secondary outcomes

- **Time to return to work** The time to return to work will be defined as the number of days required for a patient to recover post-surgery to the point where they can resume normal work duties and essential daily activities, such as walking, standing, and sitting, without significant discomfort. This period will be systematically monitored through regular assessments by the outpatient physician during standardized follow-up visits.
- **Postoperative pain** To assess the level of postoperative pain in patients, the highest pain score recorded between the 1st and 5th days postsurgery will be used as the evaluation criterion. This score will be measured using the 11-point visual analogue scale pain scale (VAS-PS) [31].
- **Anal function** To assess the anal function of patients at 1, 3, and 6 months postoperatively, this study will utilize the Cleveland Clinic Florida Incontinence Scale (CCF-IS) score [32] (range 0–20) to quantify the severity of faecal incontinence symptoms. Mild incontinence is defined by a score of 1 or 2, moderate incontinence is indicated by a score of 3, and severe incontinence is characterized by a score exceeding 4.
- **Quality of life after surgery** To assess the quality of life of patients with anal fistula at 1, 3, and 6 months postsurgery, this study will utilize the Quality of Life for Patients with Anal Fistula Questionnaire Score (QoLAF-QS) [33]. The total scores on the questionnaire range from 14 (the lowest score) to 70 (the highest score) and are calculated using the summation method. The impact on quality of life will be classified into five levels: no impact (14 points), limited impact (15–28 points), moderate impact (29–42 points), high impact (43–56 points), and very high impact (57–70 points).

## 4. Follow-up

Postoperatively, patients will be followed up by the same surgical team at the surgical clinic and through telephone interviews. All patients will be required to participate in mandatory weekly wound dressing services until the wound is completely healed, with their recovery progress systematically documented. A standardized follow-up protocol will be implemented, including outpatient visits at 1, 3, and 6 months post-surgery to assess wound healing, anal function, and quality of life. The physician's office line will remain open to monitor for complications and any abnormalities reported by patients. Follow-up will be terminated upon the earliest occurrence of one of the following: complete fistula healing, fistula recurrence, termination of data collection (due to patient relocation, change of healthcare provider, or end of the study period), or patient death.

## 5. Discussion

HHAFs present a significant treatment challenge in benign anorectal diseases due to their high internal opening, complex fistula

tracts, and extensive perianal abscess spread. Traditional surgical methods, such as excision, are often accompanied by risks of faecal incontinence and changes in the appearance of the anus, imposing considerable physiological and psychological burdens on patients. Hence, the complexity of diagnosis and treatment, combined with a high recurrence rate and postoperative faecal incontinence, poses significant challenges for both patients and surgeons. The introduction of the Hanley procedure marked a significant advancement in treating this condition and was continuously optimized by colorectal surgeons to become the mainstream treatment method. However, the posterior midline sphincterotomy involved in this procedure may damage the continuity of the external sphincter, affecting anal function. In response, we propose the BEAS procedure, which preserves the external anal sphincter while achieving closure of the internal opening through the misalignment movement of internal and external sphincter flaps, effectively preventing recurrence. Although previous studies have suggested the superiority of the BEAS procedure in terms of cure rates and preservation of anal function compared to other methods, its superiority requires further validation through comparative studies.

The BEAS procedure is anticipated to offer several unique advantages over traditional surgical methods, such as the modified Hanley procedure. The primary efficacy of BEAS is expected to be reflected in the higher wound healing rate within six months post-surgery. This accelerated healing process can be attributed to several key mechanisms inherent in the BEAS technique. The core mechanism of the BEAS surgery is to preserve the function and normal anatomical structure of the anal sphincter, while ensuring minimally invasive intervention, effective drainage, and precise closure of the internal opening. The BEAS surgery involves meticulous dissection and isolation of both the internal and external anal sphincters. This dissection facilitates the mobilization of muscle flaps to precisely close the internal opening. While preserving the external anal sphincter, the external sphincter space is left open to allow for subsequent drainage. This open approach ensures effective management of any residual infection, promoting overall healing. The strategic preservation of key anatomical features ensures that the anal region heals based on its inherent anatomical integrity. The combination of preserved sphincter function, effective drainage, and minimally invasive techniques contributes to a more favorable postoperative recovery profile. Patients undergoing the BEAS procedure are expected to experience less pain, quicker return to work, and improved quality of life compared to those undergoing the modified Hanley procedure.

This study represents the first comparative analysis between BEAS surgery and modified Hanley surgery, which is considered the mainstream HHAF procedure. The aim of this study is to investigate the advantages of BEAS surgery over traditional surgical approaches. This study provides robust evidence-based medical findings on the efficacy of BEAS in treating HHAF. Furthermore, the evaluation criteria employed in this study are notably comprehensive, encompassing both subjective and objective aspects. The purpose of this study is to provide practical evidence for the treatment of HHAF in the real world, which will involve a wide range of participants compared with RCTs. In addition, it will address both physician preferences and patient concerns, which are also crucial to the success of treatment and follow-up. RCTs are the gold standard for assessing surgical efficacy and safety, but RCTs typically have poor external validity and therefore have limited generalizability to real-world practice, which is not conducive to the initial evaluation of new technologies. Compared with retrospective studies, prospective cohort studies offer a viable solution to this issue by enabling better monitoring of patients' conditions during the follow-up period and ensuring the true reliability of the data.

However, this study has several limitations. First, given the nature of our observational research, it is important to acknowledge that there may be inherent baseline differences between the two groups, which could influence the outcomes. Second, the postoperative follow-up duration is limited to only 6 months, and it is possible that different outcomes may be observed with a longer follow-up period. Therefore, further observation is necessary to determine the long-term efficacy of this treatment. Last, it should be noted that the study includes a relatively small calculated minimum sample size and is limited to single-centre explanatory clinical trials, thereby limiting its generalizability and precluding any obvious extrapolation.

To mitigate the potential confounding effect of study design, our investigation will incorporate additional remedial measures. First, all patients will be diagnosed and treated by the same surgical team, which helps to control for biases in the intervention process. The team is particularly experienced in performing complex anal fistula surgeries, having successfully conducted over 100 BEAS procedures. This extensive experience minimizes the learning curve effect, ensuring high proficiency in the BEAS technique. The choice of treatment for each patient will be based on a comprehensive clinical assessment and thorough patient consultation. The surgeon will use imaging studies and intraoperative examinations to assess the complexity and extent of the fistula. The patient's preferences and overall health status will be considered to recommend the most appropriate surgical option. This process ensures that the selected treatment aligns with the patient's best interests and is guided by evidence-based practices and the surgeon's clinical judgment. The study aims to enhance internal validity by reducing surgeon-related variability. This approach allows for a more reliable comparison of clinical outcomes between the BEAS and modified Hanley procedures, attributing differences in outcomes to the surgical techniques themselves rather than to differences in surgical skill or approach. Second, during the data analysis, the baseline data of the two groups of patients will be compared, and the baseline internal stratification will be carried out according to the different types of full horseshoe and half horseshoe anal fistulas. Furthermore, logistic regression analysis will encompass multiple factors to examine their impact on fistula healing, thereby mitigating potential observational research biases. After determining the superior efficacy of BEAS surgery, we will conduct a large-sample, multicentre, randomized controlled study to further evaluate the long-term recurrence rates and cost-effectiveness of BEAS. This study aims to provide a more reliable evidence-based clinical foundation.

## Ethics statement

This study was reviewed and approved by the ethics committee of the local tertiary referral hospital with the approval number: 2023-1382-149-01, dated (November 13, 2023). This trial has been registered with the Chinese Clinical Trial Registry (Registration Number: ChiCTR2300078165). All participants will provide written informed consent for the publication of their anonymised case details and images. Participants will be informed of their right to withdraw from the study at any time, with assurances that their

personal privacy and the confidentiality of their data will be maintained throughout the research process.

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## Data availability statement

The study protocol and associated data will be deposited in the Chinese Clinical Trial Registry (ChiCTR) under registration number ChiCTR2300078165. Upon completion of the study, the data will be made available through the ChiCTR website or can be provided by the corresponding author upon reasonable request.

## CRediT authorship contribution statement

**Qianqian Ye:** Writing – original draft, Visualization, Resources, Methodology, Investigation, Formal analysis, Conceptualization. **Ye Han:** Validation, Supervision, Funding acquisition, Conceptualization. **Peixin Du:** Visualization, Validation, Supervision, Resources, Conceptualization. **Min Yang:** Writing – review & editing, Visualization, Resources, Methodology, Investigation, Formal analysis. **De Zheng:** Visualization, Validation, Funding acquisition, Formal analysis. **Zubing Mei:** Writing – review & editing, Software, Resources, Methodology, Investigation, Formal analysis, Conceptualization. **Qingming Wang:** Writing – review & editing, Validation, Supervision, Resources, Funding acquisition, Conceptualization.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2024.e35024.

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