

NCARE (ZNP) CLINIC REPORT

I. BRIEF INTRODUCTION

The product is a food supplement prepared according to a formula based on over thirty years of clinical experience of Professor Huang Zhengkai, who is a nationwide famous expert on treatment of hemorrhoids in China, this formula also have took advantages of principles, methods and other formulas of TCM. It is developed after repeated research and practices. In the formula, white peony root is used for nourishing blood, promoting blood circulation and preserving Yin (body fluid), Chinese angelica root (angelicae sinensis) is used for promoting the formation of new blood cells and nourishing the blood. Integrating all these herbs, this product has the functions of clearing away heat, cooling the blood, dissipating swelling, relieving pain, preserving body fluid, stopping the bleeding, moistening the dryness and dispersing the wind. So it has the advantages of being multi-functional, rapid action, good therapeutic effects and saving cost.

Versatile treatment: This means **the product** has a wide application range and it has targeted at the basic causes of diseases. It has definite therapeutic effects on internal hemorrhoids, external thrombotic hemorrhoids, combined hemorrhoids and anal fissure caused by excess heat or stasis of dampness and heat in human body, bleeding, swelling, pain and prolapse caused by the above diseases, constipation caused by dryness in human body, and senile constipation; It has prominent anti-inflammatory effects on rectitis by inhibiting vascular permeability of capillaries.

Rapid action: People speak highly of the rapid action of the product in stopping bleeding, relieving pain and improving clinical symptoms. **The product** has unique effects in stop bleeding, dissipating swelling and relieving pain. After 1-3 times of administration, the product can obviously relieve pain and stop bleeding of patient, and patients will quickly improve their major symptoms of bloody feces (feces with blood, blood dripping or blood spurting during defecation), pain, superficial fissure, whole layer fissure, mucosa congestion and erosion.

Good therapeutic effects: This means **the product** has high effective rate and low side effect and toxic effect on hemorrhoids. From the results of a clinical trial of 1000 cases in phase I, phase II and phase III in Guang'anmen Hospital affiliated to Chinese Academy of TCM, Dongzhimen Hospital affiliated to Beijing TCM University, Beijing Xuanwu Hospital of TCM, Shuguang Hospital Affiliated to Shanghai University of TCM, Yueyang Hospital Affiliated to Shanghai University of TCM, Shanghai No.4 People's Hospital, Affiliated Hospital of Nanjing University of TCM and No.2 Hospital Affiliated to Hunan University of TCM, the total effective rate of the product in treating patients with internal hemorrhoids in phase I, II and III reached 95.08%, the total effective rate for treating anal fissure in phase I, II and III reached 94.26%, and at the clinical administration dosage, no side effects and toxic effects were observed.

Cost-effective treatment: It means it saves worries, labor and money. Oral administration changes long-term inconvenience of surgical or external use therapy and the state of expensive expenses and reduces patients' frequent travel to the hospital, facilitating both patients and doctors; moreover, film coating technology replaces icing, so it's extremely suitable for the elderly.

II. PRODUCT INFORMATION

Properties: This product is film-coated tablets, it is dark brown in color after removing the film, and it's bitter and a little bit sour in taste.

Major ingredients: Chinese angelica (angelicae sinensis), white peony root, licorice root and other aid plants.

Pharmacological action: It has anti-inflammatory function, analgesic function and function in promoting defecation. It can inhibit the permeability of peritoneal capillaries of mice, increase the pain threshold of the mice stimulated by acetic acid or by heat, and shorten the coagulation time of rabbit and dog.

Function and indication: It can clear away heat, cool the blood, moisten the dryness and disperse the wind in human body. It's used for treating bleeding, swelling and pain of hemorrhoids caused by accumulation of excess heat or by stasis of dampness and heat.

Directions and dosage: 3-4 oral tablets every time, three times a day.

Storage: Sealed and kept away from moisture.

Product packing in Asia: High quality aluminum-plastic blister packaging, 40 or 20 tablets in each box.

Approval No.: National Pharmaceutical Production License: No. Z10950036

Medication guide:

1. Occasional stomach discomfort and loose stool after administration; these patients should take the product after meal.
2. Pregnant women, women in menstruation or people who have loose stool or diarrhea should use this product with caution or follow doctor's advice.
3. Patients should avoid taking spicy, hot and fishy foods and hard liquor.

III. INFORMATION ON CLINICAL TRIAL

(I) Case distribution

1. Gender distribution

	Number of cases	Male	Female	Total
Anal fissure	122	55	67	122
Internal hemorrhoid	183	116	67	183

Females are dominating in the anal fissure group while in the internal hemorrhoids group male patients are more than female patients.

2. Age distribution

	Number of cases	<20	21~30	31~40	41~50	51~60	>60	Total
Anal fissure	122	6	31	32	30	13	10	122
Internal hemorrhoid	183	7	24	43	51	31	27	183

In this clinical trial, the number of patients with age between 21 and 50 years old is the highest among patients of all ages with anal fissure; the number of patients with age between 41 and 50 years old is the highest among patients of all ages with internal hemorrhoids.

3. Clinical phases of patients with anal fissure and internal hemorrhoids

	Number of cases	Phase I	Phase II	Phase III	Total
Anal fissure	122	54	68	0	122
Internal hemorrhoid	183	75	76	32	183

Most of the patients with anal fissure in our clinical trial are in Phase I, Phase II, the patients in Phase III were not included in our observation; most of the patients with internal hemorrhoids in our clinical trial are in Phase I or Phase II, the smallest portion of patients in this study were in Phase III.

(II) Selection of patients

1. Diagnostic criteria

This criteria was drafted according to National Conference on Prevention and Treatment of Anorectal Diseases in 1975 (Names of the diseases are names in western medicine)

(1). Internal hemorrhoid

Phase I: Patient has no obvious subject symptoms, only bloody stool, blood dripping or spurting can be seen during defecation. In anoscopy, on dental line of mucosa, protuberant nodules can be observed.

Phase II: Intermittent bloody stool, blood dripping or spurting during defecation, the internal hemorrhoids prolapse, and the prolapsed hemorrhoids can draw back into the anal canal after defecation.

Phase III: The Internal hemorrhoids prolapse during defecation, or the hemorrhoids will prolapse after tiredness, long walking or coughing. The internal hemorrhoids can't draw back spontaneously after prolapse, it can only draw back into anal canal after patient supports it with hand or lies in bed.

(2). Anal fissure

Phase I: Superficial mechanical tear in anal canal, no ulcer, and no complications.

Phase II: Fissure of whole epithelium layer of anal canal, but no complications.

Phase III: Anal ulcer, complicated with anal cryptitis, hypertrophy of anal papilla, tear of hemorrhoid mucosa, superficial hidden fistula, and anal varicose vein, etc.

2. Diagnostic criteria in TCM for excess heat syndrome of patients with hemorrhoids or anal fissure

Main symptoms: Besides the characteristic symptoms of hemorrhoids and anal fissure, the patients who also have the following symptoms will be diagnosed as having excess heat syndrome.

1. Patient has bleeding, blood dripping or blood spurting during defecation; the color of blood is bright red.
2. The stool is dry and hard, the urine is in dark color, the anus swells and patient feels pain from anus.
3. Hemorrhoids prolapse out of anus during defecation or after hard work, the prolapsed hemorrhoids can draw back into anal canal spontaneously or this process needs the help of hands.
4. The tongue is bright red in color with yellow coating or thin yellow greasy coating, the patient has taut and rolling pulse or rapid and rolling pulse.
5. Anorectal examination: At the lower end of rectum, the mucosa has bulged up; there is congestion, edema, erosion and bleeding in the mucosa.

3. The standards for patients included/excluded in/from the clinical trial

(1) The standards for patients included in the clinical trial

1. The patients who conform to the diagnostic criteria of internal hemorrhoids or anal fissure.
2. The patients who conform to the diagnostic criteria of excess heat syndrome of TCM.
3. The patients with age between 18 and 65 years old.
4. Patients with Phase I, Phase II or Phase III for internal hemorrhoids, or patients with Phase I or Phase II for anal fissure.

(2) The standards for patients excluded from the clinical trial

1. Patients who don't conform to the standards for patients included in the clinical trial.
2. Patients with age younger than 18 years or older than 65 years.
3. Pregnant women, lactating women or patients with an allergic constitution.
4. Patients with serious cardiovascular diseases or cerebrovascular diseases, serious primary diseases of liver, kidney and hemopoietic system, and patients with mental illness.
5. Patients with serious complications, such as perianal abscesses and inflammation, rectal and anal cancer, rectal polyps, ulcerative colitis, loose and prolapsed rectal mucosa, etc.

6. Patients with Phase III for anal fissure.

(III) Examinations and tests

1. Examinations and tests for observation of safety of the product

- (1). Common physical examinations.
- (2). Routine laboratory tests of blood, urine and feces.
- (3). Electrocardiogram.
- (4). Liver function and renal function tests (The number of patients examined should not be less than 1/3 of all patients.)

2. Examinations and tests for observation of the therapeutic effects of the product

- (1). Relevant symptoms and signs.
- (2). Fecal occult blood test.
- (3). Anoscopy, digital rectal examination.

(IV) Observation methods in the clinical trial

1. Source and property of the product:

This food supplement is produced for international sales under NCARE trademark. This product has the functions of reducing fever and cooling blood as well as detumescence and acesodyne.

2. Administration method:

4 oral tablets/time, 3 times a day. Administer the product for 10 consecutive days then assess the therapeutic effects.

(V) Criteria for the therapeutic effects (It's the same with criteria for therapeutic effects in Phase II)

1. Internal hemorrhoids:

Clinical Cured: Bloody stool and prolapsed hemorrhoids have disappeared, in anoscopy, the mucosa of hemorrhoids has recovered to normal, and hemorrhoids are shrunk.

Prominently Effective: No obvious bleeding during and after defecation, prolapse of Phase II or Phase III of internal hemorrhoids has been improved, in anoscopy the congestion and erosion of mucosa of internal hemorrhoids have been obviously alleviated.

Effective: Bloody stool have been reduced, Phase II or Phase III of internal hemorrhoids are shrunk in size, but no obvious change in prolapse of hemorrhoids, in anoscopy the mucosa of internal hemorrhoids bulges up slightly, and the congestion, erosion of mucosa have been alleviated.

Ineffective: No change in bloody stool, prolapsed hemorrhoids and results of anoscopy.

2. Anal fissure

Clinical Cured: Symptoms have disappeared, ulcers have been healed.

Prominently Effective: Bloody stool and periodical pain caused by anal fissure have disappeared, ulcers have been improved.

Effective: Bloody stool has reduced, pain has been alleviated, and ulcers have been improved.

Ineffective: No change in both symptoms and signs.

(VI) Results of the clinical trial

1. Overview of therapeutic effects for the two diseases

	Number of cases	Cured	%	Prominently Effective	%	Effective	%	Ineffective	%	Total
Anal fissure	122	63	51.64	36	81.15	16	94.26	7	5.74	122
Internal hemorrhoid	183	82	44.81	60	77.60	32	95.08	9	4.92	183

In this clinical trial, in general, the cure rate was 47.54%; the total effective rate was 94.75%. The cure rate for anal fissure was 51.645%, the total effective rate for anal fissure was 94.26%; the cure rate for internal hemorrhoids was 44.81%, the total effective rate for internal hemorrhoids was 95.08%.

2. Comparison of therapeutic effects on internal hemorrhoids of different phases

	Number of cases	Cured	%	Prominently Effective	%	Effective	%	Ineffective	%	Total
Phase I	75	49	65.33	22	94.67	4	100	0	0	75
Phase II	76	30	39.47	28	76.32	14	94.74	4	5.26	76
Phase III	32	3	9.83	9	37.50	15	84.38	5	15.63	32

The results of Ridit analysis indicate the therapeutic effects of the product for Phase I internal hemorrhoids is better than for Phase II internal hemorrhoids, and the therapeutic effects are better for Phase II internal hemorrhoids than for Phase III internal hemorrhoids. ($P < 0.05$)

3. Comparison of therapeutic effects on anal fissure of different phases

	Number of cases	Cured	%	Prominently Effective	%	Effective	%	Ineffective	%	Total
Phase I	55	32	58.18	18	90.91	4	98.18	1	1.82	55
Phase II	67	28	41.79	21	73.13	12	91.04	6	8.96	67

The results of Ridit analysis indicate the therapeutic effects of the product for Phase I anal fissure is better than for Phase II anal fissure. ($P < 0.05$)

4. Improvements in clinical symptoms

	Blood-stained	Blood dripping	Blood spurting	<5 minutes	5~30 minutes	>30 minutes
Number of cases Before treatment	61	42	10	55	37	11
Number of cases After treatment	7	2	0	13	4	1

Comparison of bloody stool before and after treatment: $X^2 = 177.90$, $P < 0.0001$, It indicates that bloody stool had been prominently reduced after treatment; comparison of pain before and after treatment: $X^2 = 119.58$, $P < 0.0001$, this indicates pain symptom had been prominently improved after treatment.

5. Improvements in examinations before and after treatment

(1). Analysis on improvements in anoscopy examination of internal hemorrhoids before and after treatment:

	Number of cases	Mucosal congestion	Mucosal erosion	Hemorrhagic spots on mucosa
Before treatment	183	129	4	54
After treatment	183	70	4	1

Comparison of mucosal congestion before and after treatment: $X^2 = 37.05$, $P < 0.001$, It indicates mucosal congestion had been prominently improved after treatment; statistical analysis on mucosal erosion: $X^2 = 2.69$, $P > 0.05$, It indicates there is no significant improvements in mucosal erosion after treatment; statistical analysis on mucosal ulcer: $X^2 = 0.13$, $P > 0.05$, It indicates there is no significant improvements in mucosal ulcer after treatment; comparison of mucosal hemorrhagic spots before and after treatment: $X^2 = 57.86$, $P < 0.001$, It indicates hemorrhagic spots on mucosa had been significantly improved after treatment.

(2). Analysis on improvements in local physical examination of patients with anal fissure after treatment:

	Number of cases	Superficial fission	Whole layer fissure	Anal fissure with ulcer	Total
Before treatment	122	54	49	19	122
After treatment	122	9	17	14	122

Comparison of superficial fissure before and after treatment: $X^2 = 41.43$, $P < 0.0001$, It indicates superficial fissure had been significantly improved after treatment; statistical analysis on improvements in whole layer fissure: $X^2 = 19.96$, $P < 0.0001$, It indicates there is significant improvements after treatment; comparison of anal fissure with ulcer: $X^2 = 0.56$, $P > 0.05$, It indicates there is no significant improvements in anal fissure with ulcer after treatment.

6. Laboratory tests and ECG examination:

There was no change in the results of blood routine test, urine routine test, BUN test, liver function test and ECG examination before and after treatment.

(VII) Adverse reactions

In this study we observed a total of 305 patients; all the patients had no allergic reactions or other adverse reactions.

(VIII) Typical cases

(Internal hemorrhoids - Phase I)

Case 1: Mr. Yang, male, 27 years old, he visited doctor on December 19, 1996.

The patient had defecated bloody stool for two weeks, during defecation the blood spurted out with a rather high volume, the feces was dry and hard, but he has no pain during defecation and no prolapsed hemorrhoids. The patient administered a suppository for treating hemorrhoids, but no obvious effects were observed. Physical examination: body temperature: 36.1°C, pulse: 70 times/minute, respiration: 10 times/minute, blood pressure: 15/9KPa. The results of physical examination on heart, lung and abdominal part were normal, the patient had red tongue with yellow coating, and his pulse was taut and slippery. Local physical examination: Appearance of anus (-), in anoscopy, the mucosa bulged up at 3, 7 and 11 o'clock in lithotomy position, color of the mucosa was dark red, protrusion of mucosa at 11 o'clock was the highest, there was erosion on the surface of the mucosa, and hemorrhagic spots could be observed. Diagnosis in western medicine: Phase I Internal Hemorrhoids. Diagnosis in TCM: Syndrome of excess heat accumulated in intestine. Treatment: Oral administration of **NCARE product**, 4 tablets/time, three times per day. After 6 days of administration of the product, bloody stool had disappeared, in anoscopy congestion and erosion of mucosa had been improved significantly, and hemorrhagic spots had disappeared; after 10 days of administration of the product, all symptoms had disappeared, in physical examination the patient had tongue in light red color with thin and white coating, his pulse was taut and

clear, in anoscopic examination, his anal mucosa had recovered to normal. All laboratory tests were normal before and after treatment.

(Internal hemorrhoids - Phase II)

Case 2: Wang Peichang, male, 62 years old, he visited doctor on August 31, 1996.

The patient had remittent bloody stool and prolapse of something from anus, the symptoms had worsened for 5 days when he visited doctor, and he administered an ointment, but no obvious effects, so the patient visited doctor in hospital. Local physical examination: in anoscopy, there was a combined hemorrhoids at 3, 7 and 11 o'clock in lithotomy position, protrusion of mucosa at 11 o'clock was the highest, and there was pale fibrosis in mucosa, digital rectal examination (-). Clinical diagnosis in TCM: Hemorrhoids (Damp-heat type). Diagnosis in western medicine: Phase II internal hemorrhoids. Treatment: Oral administration of **NCARE product** for 10 consecutive days, 4 tablets per time, three times per day. Results of treatment: The bleeding of anus had disappeared after 10 days of administration of the product, and the hemorrhoids basically disappeared after 10 days of administration of the product. Therapeutic effects: The patient was clinically cured.

(Anal fissure - Phase I)

Case 3: Wang Gang, male, 25 years old, outpatient.

The patient had repeated bloody stool during defecation and anal pain after defecation for two weeks. Physical examination: Tongue of the patient was pale in color with white and thin coating, his pulse was wiry and taut, superficial fissure could be observed on skin of anus at 6 o'clock in lithotomy position. The bleeding of anus was stopped after 4 days of administration of **NCARE product**, pain symptom disappeared and anal fissure healed after 7 days of administration of the product. The patient was followed up for one month, there was no recurrence.

(Anal fissure - Phase II)

Case 4: Mrs. Lu, female, 56 years old, outpatient.

The patient had pain and bleeding during defecation and difficulty in defecation for three years, she visited doctor on November 1, 1996. In physical examination, an ulcer fissure at 5 o'clock in lithotomy position was identified, she was diagnosed as having Phase II anal fissure, and the doctor prescribed **NCARE product** to her. After 3 days of administration of the product, bleeding and pain had been obviously alleviated, after 6 days of administration of the product, blood-stained stool had disappeared, the anal ulcer fissure had shrunk to less than half of the original size, after 10 days of administration of the product, she already had no discomfort in anal part, all symptoms disappeared, in local physical examination, the doctor observed that the ulcer fissure had healed.

(IX) Conclusions

Hemorrhoids and anal fissure accounts for more than 70% of anorectal diseases, the major clinical manifestation of the two diseases are bloody stool, pain, prolapse, long defecation time and difficulty in defecation, etc. In order to relieve patients from hemorrhoids and anal fissure, the famous and experienced doctor of TCM, Mr. Huang Zhengkai, who is also a Professor of Hunan University of TCM, jointly developed

the oral product **NCARE ZNP**, the formula is based on many years of experience in clinical application and practices of Professor Huang Zhengkai, the main functions of the product are clearing away heat, cooling blood, dissipating swelling, relieving pain, shrinking the wound, stopping the bleeding, moisturizing intestine and promoting defecation.

Based on the results of clinical trial, relevant pharmacodynamic data and results of pharmacological experiments in Phase II clinical trial, we conducted Phase III clinical trial of **the product**. After clinical observation of 183 cases of internal hemorrhoids and 122 cases of anal fissure, results from the statistical analysis has proved that the product has the following advantages in efficacy and drug safety:

1. Analysis on the total therapeutic effects: The total effective rate for treating Phase I and Phase II anal fissure was 94.26%, the effective rate for Phase I anal fissure was 98.18%, the effective rate for Phase II anal fissure was 91.04%, which suggests that this product has prominent efficacy in treating Phase I and Phase II anal fissure, $P < 0.05$. The total effective rate for treating Phase I, Phase II and Phase III internal hemorrhoids was 95.08%, the effective rate for Phase I internal hemorrhoids was 100%, the effective rate for Phase II internal hemorrhoids was 94.74%, the effective rate for Phase III internal hemorrhoids was 84.38%. From statistical analysis of the results, the therapeutic effects is better for Phase I internal hemorrhoids than for Phase II internal hemorrhoids, and the therapeutic effects is better for Phase II internal hemorrhoids than for Phase III internal hemorrhoids.
2. Analysis on the improvements in symptoms and signs after treatment: There were obvious improvements in bloody stool (blood-stained stool, dripping of blood and spurting of blood during defecation), pain, superficial fissure, whole layer fissure, mucosal congestion and erosion in patients. There was significant difference comparing the symptoms and signs before and after treatment, which suggests that this product has prominent effects in stopping bleeding and relieving pain cause by anal fissure and internal hemorrhoids of different phases.
3. 305 patients were observed in this clinical trial, all patients had no adverse reactions in gastrointestinal tract and no allergic reaction. The product had no other side effects and toxic effects, it had no obvious impact on heart function, liver function and renal function, all these information suggests that the product is safe and reliable in clinical application.

(X) Assessment

According to the observation on 305 patients in Phase III of clinical trial, the results suggest that this product has definite therapeutic effects on Phase I and Phase II internal hemorrhoids, and on Phase I and Phase II anal fissure, It can significantly improve symptoms, It's particularly effective for patients with bloody stool, pain, fresh superficial anal fissure and injury, inflammatory mucosal congestion and erosion. In clinical application **NCARE ZNP** has been proved to have the following functions:

1. This product has the function of clearing away heat, cooling blood, stopping bleeding, helping to shrink the wound, and promoting healing process.
2. This product has prominent effects in relieving or eliminating pain of patients with Phase I or Phase II anal fissure, which confirms that this product has analgesic function in clinical application; this conforms to the results of pharmacodynamic experiments.

3. This product is used for treating excess heat syndrome caused by evil wind, dryness, dampness and heat; It is suitable for patients with heat in blood and dry wind on skin, dry intestine and difficulty in defecation, swelling external hemorrhoids, thrombosed hemorrhoids, edema, ante partum anal fissure, etc.
4. A total of 305 patients were observed in clinical trial, patients had no adverse reactions, and the product had no side effects and toxic effects. It is safe and reliable.

(XI) Institutions and clinical staff participating in the clinical research of NCARE ZNP product:

The organizing institution: Guang'anmen Hospital of China TCM Academy

Directors of the clinical research:

Yin Haibo	Associate Professor	Director of the Department of Scientific Research
Zhao Baoming	Associate Professor	Deputy Chief of Anorectal Diseases Department

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Zhao Baoming	Associate Professor	Deputy Chief of Anorectal Diseases Department
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Participating unit: Anorectal Diseases Department of Guang'anmen Hospital of China TCM Academy

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Some Terms And Definitions In This Clinical Report

TCM: Alternative Medicine (Herbal Treatment: Chinese Traditional Medicine)

Yin: One of two opposing forces in traditional Chinese philosophy and medicine.

Prolapsus: (=Prolapse): The falling down or slipping of a body part from its usual position or relations.

Rectitis: (=Proctitis): Inflammation of the rectum.

Cryptitis: Inflammation of a crypt (as an anal crypt).

Cerebrovascular: Of or involving the cerebrum and the blood vessels supplying it.

Hematopoiesis: (=Hemopoiesis): The formation of blood or of blood cells in the living body.

Hemopoietic: Pertaining to the formation of blood or blood cells.

Perianal: Around the anus.

Colonitis: (=Colitis): Inflammation of the colon.

Anoscopy: Visual examination of the anal canal with an anoscope.

Detumescence: Reduction, subsidence, or lessening of a swelling, especially the restoration of a swollen organ or part to normal size.

Acesodyne: Mitigating or relieving pain.

Ridit Analysis: It is a statistical method for comparing ordinal-scale responses.

Lithotomy: Surgical incision of the urinary bladder for removal of a calculus.

Anoscope: Medical device used to examine the anus and rectum.

Anorectal: Referring to both the anus and rectum.

Pharmacodynamics: A branch of pharmacology dealing with the reactions between drugs and living systems.

Thrombosed: Affected with or obstructed by a clot of coagulated blood.