A Three-Arm, Randomized, Placebo-Controlled, Double-Blind Phase 3 Study to Evaluate the Safety and Efficacy of Once-Daily and Twice-Daily Dosing of a Novel Hydrocortisone Acetate 90 mg Suppository Formulation Administered with the Sephure® Suppository Applicator in Subjects with Ulcerative Colitis of the Rectum

04/04/2025 05:46:50

Main Information

Primary registry identifying number
LBCTR2024015424

Protocol number
CHS1221

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency
16/11/2023

Primary sponsor
Cristcot HCA LLC

Primary sponsor: Country of origin
United States

Date of registration in primary registry
07/03/2024

Date of registration in national regulatory agency
16/11/2023

Public title
A Three-Arm, Randomized, Placebo-Controlled, Double-Blind Phase 3 Study to Evaluate the Safety and Efficacy of Once-Daily and Twice-Daily Dosing of a Novel Hydrocortisone Acetate 90 mg Suppository Formulation Administered with the Sephure® Suppository Applicator in Subjects with Ulcerative Colitis of the Rectum

Acronym
cessa

Scientific title
A Three-Arm, Randomized, Placebo-Controlled, Double-Blind Phase 3 Study to Evaluate the Safety and Efficacy of Once-Daily and Twice-Daily Dosing of a Novel Hydrocortisone Acetate 90 mg Suppository Formulation Administered with the Sephure® Suppository Applicator in Subjects with Ulcerative Colitis of the Rectum

Acronym
cessa

Brief summary of the study: English
A Three-Arm, Randomized, Placebo-Controlled, Double-Blind Phase 3 Study to Evaluate
the Safety and Efficacy of Once-Daily and Twice-Daily Dosing of a Novel Hydrocortisone Acetate
90 milligrams (mg) Suppository Formulation Administered with the Sephure Suppository
Applicator in Subjects with Ulcerative Colitis of the Rectum.

Brief summary of the study: Arabic

دراسة من ثلاثة مجموعات، عشوائية، مراقبة بدواء وهمي، مزدوجة التعمية، ومن المرحلة الثالثة، لتقييم سلامة وفعالية تحميلة ذات تركيبة جديدة عند استعمالها مرة واحدة في اليوم أو مرتين في اليوم ،Sephure® ملغ المستعملة بواسطة قضيب التحميلة90من أسيتات الهيدروكورتيزون لدى المرضى المصابين بالتهاب القولون التقرحي في المستقيم"

Health conditions/problem studied: Specify

Subjects with Ulcerative Colitis of the Rectum

Interventions: Specify

Hydrocortisone Acetate 90 milligrams (mg) Suppository Formulation Administered with the Sephure Suppository Applicator

Key inclusion and exclusion criteria: Inclusion criteria

Males or non-pregnant, non-lactating females aged 18 years and older.
2. Able to provide a signed informed consent.
3. Confirmed diagnosis of UC with an endoscopic score of 2-3 no further than 15 cm (5.9 inches) from the anal verge as assessed by the endoscopy performed at Visit 2. For clarity, subjects with an endoscopic score of 2-3 up to 15 cm from the anal verge and deceleration of disease severity (endoscopic score 0-1) beyond 15 cm from the anal verge are inclusionary. Note: Subjects may have a history of more extensive UC (e.g., pancolitis), but must have an endoscopic score of 2-3 only in the rectum at the time of the screening endoscopy.
4. Modified Mayo sub-score for stool frequency of 1-3 at Screening Visit (Visit 1) and Baseline Visit (Visit 3).
5. Modified Mayo sub-score for rectal bleeding of 0-2 at Screening Visit (Visit 1) and Baseline Visit (Visit 3).
6. Modified Mayo endoscopic sub-score of 2-3 at endoscopy (Visit 2) as determined by Central Reading.
7. Modified Mayo Total Score (without physician global assessment) of 4-8.
8. Females of childbearing potential must be either sexually inactive (abstinent) for 21 days prior to the first dose and willing to be sexually inactive throughout the study or must be using one of the following acceptable methods of birth control:
a) Surgically sterile (bilateral tubal ligation, hysterectomy, or bilateral oophorectomy) for a minimum period of 1 month prior to screening;
b) Intrauterine device in place for at least 1 month prior to screening;
c) Barrier methods (condom, diaphragm) with spermicide for at least 21 days prior to screening and willing to continue throughout the study; or
d) Hormonal contraceptives for at least 6 weeks prior to screening.
9. Postmenopausal females with amenorrhea for at least 12 months prior to screening.
10. Subjects willing to abstain from receiving anal sex, anal bleaching, anal waxing, etc.
11. Availability of all the screening assessment results, such as: serum pregnancy test (for females of childbearing potential), medical history, concomitant medication, AEs, vital signs, physical examination, electrocardiogram (ECG), documented endoscopy assessment, complete blood count, clinical chemistry and serology, urinalysis and stool test results.
12. Subjects may be allowed to be re-screened for the study after consultation and approval from the Global Medical Monitor but may be enrolled (randomized) only once.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

100

Key inclusion and exclusion criteria: Exclusion criteria

Subjects will be excluded from the study if they meet any of the following criteria:
1. Endoscopic sub-score of 0 or 1 within 15 cm from the anal verge assessed by the Investigator during the endoscopy at Visit 2 (no video sent to Central Reading).
2. Endoscopic sub-score of 2 or 3 beyond 15 cm from the anal verge assessed by the Investigator during the endoscopy at Visit 2 (no video sent to Central Reading).
3. Endoscopic sub-score of 0 or 1 as assessed by the Central Reading using the using the video obtained during the endoscopic procedure at Visit 2.
4. History or current diagnosis of bacterial or other infectious colitis, radiation-enteritis and radiation-proctitis, Crohn's disease, collagenous colitis and indeterminate colitis.
5. Prior gastrointestinal surgery except appendectomy, cholecystectomy, hiatal hernia repair, Nissen Fundoplication wrap around lower esophagus, Heller myotomy of lower esophageal sphincter, gastric sleeve, limited small bowel resection, partial gastrectomy/Billroth I or II, and hernia.
6. Concomitant active gastrointestinal disease affecting the colon or rectum (except irritable bowel syndrome) or distortion of intestinal anatomy.
7. Bleeding hemorrhoids at the time of screening.

8. Acute diverticulitis at the time of screening.
9. Acute pancreatitis at the time of screening.
10. Uncontrolled, previously diagnosed type 1 or 2 diabetes mellitus.
11. Uncontrolled abnormal thyroid function.
12. Mean value for triplicate sitting SBP >160 mm Hg and/or DBP >100 mm Hg after at least a 5-minute seated rest at the Screening visit. The Investigator or the treating physician is allowed to adjust background blood pressure medication(s) to lower blood pressure values in order for the subject to be re-assessed for randomization eligibility.
13. Clinically significant ECG abnormality at screening that requires further diagnostic evaluation or intervention (e.g., new, clinically significant arrhythmia or a conduction disturbance).
14. Serum hemoglobin levels <7.5 g/dL (<4.65 mmol/L).
15. Indication of impaired liver function as shown by an abnormal liver function profile at Screening (e.g., repeated values of aspartate aminotransferase [AST], alkaline phosphatase [ALP], and alanine aminotransferase [ALT] ≥ 2 × the upper limit of normal).
16. History of sclerosing cholangitis, cirrhosis, or hepatic impairment.
17. Renal disease manifested by serum creatinine >2.0 mg/dL (176.8 µmol/L).
18. Positive test result at screening for cytomegalovirus, tuberculosis (confirmed as active with xray), human immunodeficiency virus, hepatitis B or C infection.
19. History of ocular herpes simplex or ocular varicella zoster infection.
20. History of unresolved malignant disease, with the exception of basal cell carcinoma and/or squamous cell carcinoma in situ of the skin.
21. Diagnosis of Addison's disease, congenital adrenal hyperplasia, or other form of adrenal insufficiency.
22. Subjects with abnormal response to the ACTH stimulation test performed at the screening visit (Visit 1).
23. Active systemic infection.
24. Toxic megacolon, fistula, perforation, or abscess.
25. Uncontrolled psychiatric disorders or seizure disorders.
26. History of non-responsive UC to steroid treatment.
27. History of medical condition requiring use of inhaled steroids during the study (for treatment of asthma, COPD, etc.).
28. History of drug or alcohol abuse within the last 6 months. Alcohol abuse is defined as more than 14 drinks per week for men and more than 7 drinks per week for women.
29. Other current diagnosis of severe, progressive, or uncontrolled renal, hepatic, hematologic, endocrine, pulmonary, cardiac, neurologic, psychiatric, or cerebral diseases.
30. History of evidence of any medical condition that would, in the opinion of the Investigator, make the subject unsuitable for the study.
31. Positive stool test result at screening for enteric pathogens, Clostridium difficile, or presence of ova and parasites.
32. Vaccination with a live-attenuated vaccine within 28 days prior to randomization or that will occur during the study (other types of vaccines including those for COVID-19 are allowed).
33. Allergies to hydrocortisone acetate or to any other ingredients of the investigational product.
34. Taking a permitted medication outside of the permitted criteria (Section 5.8.1).
35. Taking a prohibited medication (Section 5.8.2).
36. Pregnant, confirmed with a positive serum test for pregnancy at screening, or lactating females and females of childbearing potential who do not meet the inclusion criteria (Section 4.1).
37. Participation in another research study for an investigational drug within 30 days of the Screening Visit and during the study

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Dose-response

Trial scope: Specify scope

N/A

Study design: Allocation

Randomized controlled trial

Study design: Masking

Blinded (masking used)

Study design: Control

Placebo

Study phase

3

Study design: Purpose

Other

Study design: Specify purpose

To Evaluate the Safety and Efficacy

Study design: Assignment

Study design: Specify assignment

Parallel

N/A

IMP has market authorization

No

IMP has market authorization: Specify

Name of IMP

hydrocortisone acetate

Year of authorization

Month of authorization

Type of IMP

Others

Pharmaceutical class

Corticosteroids

Therapeutic indication

Ulcerative Colitis of the Rectum.

Therapeutic benefit

To evaluate the efficacy of two dosage regimens of the study drug (hydrocortisone acetate 90 mg suppository) administered with the Sephure suppository applicator compared to placebo in the treatment of ulcerative colitis (UC) of the rectum using the Modified Mayo Score

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

None retained

Biospecimen description

N/A

Target sample size

189

Actual enrollment target size

Date of first enrollment: Type

Actual

Date of first enrollment: Date

01/09/2020

Date of study closure: Type
Actual

Date of study closure: Date
31/05/2024

Recruitment status
Recruiting

Recruitment status: Specify

Date of completion
31/05/2024

IPD sharing statement plan
No

IPD sharing statement description
No IPD sharing plan .

Additional data URL

Admin comments

Trial status
Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
IND No.	122900
EudraCT No	2019-003596-19

Sources of Monetary or Material Support

Name
Cristcot HCA LLC

Secondary Sponsors

Name
N/A

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Eliane Nase	MCT-CRO, Berytech Technology and Health, 5th Floor Damascus Road, Beirut, Lebanon	Lebanon	961 81 115830	eliane.nasr@mct-cro.com	Country Manager
Scientific	Mahmoud Othman	Nini Hospital	Lebanon	+ 961 3 54 56 51	mmo_1983@yahoo.com	PI
Scientific	Dr.Bilal Hotayt	Bellevue Medical Center	Lebanon	+961 3 602213	bilal.hotayt@hotmail.fr	PI
Scientific	Lara Hassoun	Hammoud Hospital University Medical Center	Lebanon	+961 037 11115	dr.larahassoun@gmail.com	PI
Scientific	Khalil Bedran	Saint George Hospital University Medical Center	Lebanon	+961 348 1408	khalil.bedran02@gmail.com	PI

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Nini Hospital	Mahmoud Othman	Gastroenterology	Pending
Bellevue Medical Center	Bilal Hotayt	Gastroenterology	Pending
Hammoud Hospital University Medical Center	Lara Hassoun	Gastroenterology	Pending
Saint George Hospital University Medical Center	Khalil Bedran	Gastroenterology	Pending

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Nini Hospital	15/11/2023	Kamleh Ibrahim	kamleh.ibrahim@hopitalnini.com	96170500375
Hammoud Hospital University Medical Center	29/11/2023	Ghada Aoun	medical@hhumc.org.lb	961 3 408947

Countries of Recruitment

Name
Bulgaria
Denmark
France
Georgia
India
Italy
Republic of Moldova
Philippines
Poland
Romania
Russian Federation
Saudi Arabia
South Africa
Spain
Turkey
Ukraine
United States of America
Viet Nam

Health Conditions or Problems Studied

Condition	Code	Keyword
Ulcerative Colitis of the Rectum	Ulcerative (chronic) proctitis (K51.2)	Ulcerative Colitis of the Rectum

Interventions

Intervention	Description	Keyword
Hydrocortisone acetate 90 mg or placebo	Hydrocortisone acetate 90 mg or placebo will be administered as a rectal suppository with a Sephure suppository applicator. Two arms of the study will receive different dosage regimens of hydrocortisone acetate, and the third arm will receive placebo. All subjects will administer the study drug twice a day;	Hydrocortisone acetate 90 mg

Primary Outcomes

Name	Time Points	Measure
The primary efficacy endpoint is the proportion of subjects with clinical remission at the End of Treatment Visit (Visit 7).	The primary efficacy endpoint is the proportion of subjects with clinical remission at the End of Treatment Visit (Visit 7). Clinical remission is defined as the Modified Mayo Score of 0 to 2, with stool frequency sub-score of 0 or 1 (minimum 1 point decrease from a Baseline score of 1 or 2), rectal bleeding sub-score of 0, and endoscopic sub-score of 0 or 1.	Clinical remission is defined as the Modified Mayo Score of 0 to 2, with stool frequency sub-score of 0 or 1 (minimum 1 point decrease from a Baseline score of 1 or 2), rectal bleeding sub-score of 0, and endoscopic sub-score of 0 or 1

Key Secondary Outcomes

Name	Time Points	Measure
Rectal bleeding	Endpoints will be evaluated hierarchically with Baseline (Day 1/Visit 3) compared to End of Treatment (Day 29/Visit 7) and then Follow Up (Day 15/Visit 5)	Rectal bleeding sub-score of 0 (MMDAI).
Reduction of stool frequency	Endpoints will be evaluated hierarchically with Baseline (Day 1/Visit 3) compared to End of Treatment (Day 29/Visit 7) and then Follow Up (Day 15/Visit 5):	Reduction of stool frequency

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files