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A trial of the synthetic cannabinoid ART27.13 to stimulate appetite in patients with cancer anorexia and weight loss

Submission date
06/04/2021

Recruitment status
No longer recruiting

Registration date
09/04/2021

Overall study status
Ongoing

Last Edited
07/11/2025

Condition category
Cancer

[ ] 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
Anorexia is defined as the lack or loss of appetite. Anorexia in cancer patients may result from the cancer and/or its treatment with radiation or chemotherapy. It is common for patients with cancer to lose weight. Anorexia and the resulting weight loss can affect a patient's health, often weakening their immune system and causing discomfort and dehydration. A weight loss of more than 5% can predicted a poor outcome for cancer patients and a lower response to chemotherapy. Drugs that increase a patient's appetite (appetite stimulants) have been used for treatment of cancer anorexia, but none have been approved for this use.
Anorexia is an issue for many patients with cancer, and ART27.13 may increase appetite, lean body mass, and weight in these patients.
This study will assess the safety of ART27.13 and determine the most effective, safe dose to be given to patients. The study will also assess the activity of ART27.13 in cancer patients with anorexia and weight loss by measuring increased lean body mass, weight gain, and improvement of anorexia.

Who can participate?
Male and female patients over the age of 18 with certain types of cancer who are either not on anticancer therapy or are on a stable daily doses of certain treatments and have documented weight loss of >5% of their body weight in the past 6 months.

What does the study involve?
Patients who agree to participate in the study, will be asked to sign the study Informed Consent Form. Involvement in the study will take a maximum of 18 weeks in total, during which patients will be required to attend a number of clinic visits to undergo a series of assessments. The following assessments will be performed (please note, not all assessments are performed at every visit):
- General medical and physical examinations, including height and weight measurement
- A pregnancy test
- Vital signs (assessment of heart rate, breathing rate, blood pressure and body temperature)
- An electrocardiogram (also known as an 'ECG')

- Blood samples, for routine safety tests, for checking levels of the study drug in the body and for checking of levels of certain components of the blood which may indicate a response to the drug.
- A DEXA scan, which is a type of x-ray used to measure the amount of lean body mass (muscle)
- A series of questionnaires which aim to assess patients' symptoms of anorexia and quality of life
- Complete a diary for any steroids taken

What are the possible benefits and risks of participating?
It is not known whether there will be any benefit for the patients in this study. However, there is data to suggest that ART27.13 may help increase appetite, and thereby lead to patients maintaining (not losing) and even gaining weight.

Where is the study run from?
The CAReS study will be run at the following hospitals in the United Kingdom and Ireland:
- Western General Hospital, Edinburgh
- The Royal Marsden NHS Foundation Trust, London (Sutton and Chelsea)
- Hammersmith Hospital, London
- St James's Hospital, Leeds
- The Christie Hospital, Manchester
- St James's Hospital, Dublin
- Royal Derby Hospital, Derby
-The VCTC, Castle Donington, Oxford and Wellingborough
-University Hospital, Hairmyers, Glasgow

When is the study starting and how long is it expected to run for?
February 2020 to March 2026

Who is funding the study?
The study is funded by Artelo Biosciences Ltd. (UK)

Who is the main contact?
Dr Barry JA Laird, Barry.laird@ed.ac.uk
Dr Paula Daunt, p.daunt@artelobio.com

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2020-000464-27

Integrated Research Application System (IRAS)
278450

ClinicalTrials.gov (NCT)
Nil Known

Protocol serial number
ART27.13-100, IRAS 278450

Study information

Scientific Title
Cancer Appetite Recovery Study (CAReS): a phase 1/2 trial of the synthetic cannabinoid ART27.13 in patients with cancer anorexia and weight loss

Acronym
CAReS

Study objectives
The drug ART27.13 is safe and can be utilized to improve the symptoms of anorexia in patients with cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 21/09/2020, North East – Tyne & Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8084; tyneandwearsouth.rec@hra.nhs.uk), ref: 20/NE/0198

Study design
Open-label multicenter dose-escalation study followed by a randomized double-blind placebo-controlled multicenter study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cancer patients with anorexia and weight loss

Interventions
Current interventions as of 28/11/2023:

ART27.13 (or the matching placebo in Stage 2) is orally administered to patients once daily for up to 12 weeks.

Stage 1 (12 weeks) assesses ART27.13 in escalating doses of 150, 250, 400, and possibly 650 µg /day.

In Stage 2 (12 weeks), patients are randomized in a 3:1 ratio to ART27.13 or matching placebo. The randomization schedule is kept at the Pharmacy at each site.

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Previous interventions:

ART27.13 (or the matching placebo in Stage 2) is orally administered to patients once daily for up to 12 weeks.

Stage 1 (12 weeks) assesses ART27.13 in escalating doses of 150, 250, 400, and possibly 650 µg /day.

In Stage 2 (12 weeks), patients are randomized in a 4:1 ratio to ART27.13 or matching placebo. The randomization schedule is kept at the Pharmacy at each site.

Intervention Type
Drug

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
ART27.13

Primary outcome(s)
Stage 1: Safety is evaluated by the assessment of the type, frequency and severity of adverse drug effects throughout the 12 week treatment period and the 30-day follow up period and routine chemistry, haematology, urinalysis, vital signs and ECGs at baseline, weekly for 4 weeks, bi-weekly for 8 weeks and at the 30 day follow up period.
Stage 2: the change in lean body mass is determined by weight and dual-energy X-ray absorptiometry (DEXA) body scans at 12 weeks, and the change in anorexia is determined by visual analogue scale (VAS) at baseline, week 4, week 8, week 12 and at the 30-day follow up visit

Key secondary outcome(s))
Stage 1:
1. The change in lean body mass is determined by weight and DEXA scans at 12 weeks
2. The change in anorexia is determined by VAS and Functional Assessment of Anorexia and Cachexia Therapy (FAACT) questionnaire at baseline, week 2 (FAACT only), week 4, week 8, week 12 and at the 30-day follow up visit
3. The change in performance status as per the Karnofsky Performance Status (KPS) is determined at baseline, weekly for the first 4 weeks, then once every 4 weeks for the remaining 8 weeks of treatment, and at the 30-day follow up visit.
4. Quality of life (QoL) is measured using the FAACT questionnaire, the patient-generated subjective global assessment (PG-SGA), the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C15-PAL and revised Edmonton Symptom Assessment Scale (r-ESAS) questionnaires at baseline, 2 weeks, 4 weeks and 8 weeks and at the 30-day follow-up.
5. The pharmacokinetics of ART27.13 is determined by analyzing blood concentrations of ART27.13 in samples taken at baseline, at 1, 2, 4, 6 and 24 hours post dosing on the first day of dosing (cycle 1 day 1), and again after 4 weeks (cycle 2 day 1) and 8 weeks (cycle 3 day 1).

Stage 2:
1. Safety is evaluated by the assessment of the type, frequency and severity of adverse drug effects throughout the 12 week treatment period and the 30-day follow up period and routine chemistry, hematology, urinalysis, vital signs and ECGs at baseline, weekly for 4 weeks, bi-weekly for 8 weeks and at the 30 day follow up period.
2. QoL is measured using the FAACT, PG-SGA, EORTC QLQ-C15-PAL and r-ESAS questionnaires at baseline, 2 weeks, 4 weeks, 8 weeks and at the 30-day follow-up.

Completion date
30/03/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 28/11/2023:

1. Have cancer (except those excluded by the exclusion criteria) documented by histopathology or cytology.
2. Have anorexia as determined by self-reported decrease or lack of appetite or aversion to food.
3. Have documented, unintentional weight loss of >5% of body weight in the past 6 months dating back from the date of enrollment.
4. Patients are on either:
4.1 no anti-cancer therapy for the 2 weeks before enrollment and are not expected to have anti-cancer therapy for the first 12 weeks after the first dose of ART27.13 (Stage 1) or if in Stage 2, after the start of ART27.13/placebo; or

4.2 stable daily dosing from 2 weeks before enrolment and expected to be on such therapy for another 12 weeks of anti-cancer monotherapy therapy with hormonal therapy for breast, prostate, or uterine cancer or capecitabine for breast or colon cancer.
5. Estimated life expectancy of at least 12 weeks as judged by the Investigator based on clinical impression.
6. Have a KPS of >50.
7. At least 18 years of age at the time of enrollment.
8. Adequate hematological, renal, and hepatic function based on laboratory values obtained within 14 days of randomization:
8.1. Absolute neutrophil count ≥ 1.0 X 109/L
8.2. Platelets ≥75 x 10^9/L
8.3. Serum creatinine ≤ 1.5 times upper limit of laboratory normal (ULN)
8.4. Total serum bilirubin ≤ 1.5 times ULN (≤ 3.0 times ULN if patient has been diagnosed with Gilbert's syndrome)
8.5. Aspartate aminotransferase (AST), alanine aminotransferase (ALT), and alkaline phosphatase (AP) ≤ 2.5 times ULN
9. For women of child-bearing potential and for men with partners of child-bearing potential, patient must agree to take contraceptive measures for the duration of treatments and for 6 months after the last study treatment.
10. Understand and voluntarily sign and date an Informed Consent Document ICD prior to any study related assessments/procedures.
11. Willing and able to adhere to the study visit schedule and other protocol requirements.
12. Agree to not driving or operating heavy machinery for the first 4 weeks of treatment or longer if adverse events warrant as known adverse events of ART27.13 include dizziness and somnolence.

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Previous inclusion criteria:

1. Have cancer (except those excluded by the exclusion criteria) documented by histopathology or cytology.
2. Have anorexia as determined by self-reported decrease or lack of appetite or aversion to food.
3. Have documented, unintentional weight loss of >5% of body weight in the past 6 months dating back from the date of enrollment.
4. Patients are on either:
4.1 no anti-cancer therapy for the 2 weeks before enrollment and are not expected to have anti-cancer therapy for the first 12 weeks after the first dose of ART27.13 (Stage 1) or if in Stage 2, after the start of ART27.13/placebo; or
4.2 stable daily dosing from 2 weeks before enrolment and expected to be on such therapy for another 12 weeks of anti-cancer monotherapy therapy with hormonal therapy for breast, prostate, or uterine cancer or capecitabine for breast or colon cancer.
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Gilbert’s syndrome)
8.5. Aspartate aminotransferase (AST), alanine aminotransferase (ALT), and alkaline phosphatase (AP) ≤ 2.5 times ULN
9. For women of child-bearing potential and for men with partners of child-bearing potential, patient must agree to take contraceptive measures for the duration of treatments and for 6 months after the last study treatment.
10. Understand and voluntarily sign and date an Informed Consent Document ICD prior to any study related assessments/procedures.
11. Willing and able to adhere to the study visit schedule and other protocol requirements.
12. Willing to avoid sun exposure by using protective measures such as sunscreen, clothing, and sunglasses during therapy because the phototoxicity of ART27.13 has not been studied in animals.
13. Agree to not driving or operating heavy machinery for the first 4 weeks of treatment or longer if adverse events warrant as known adverse events of ART27.13 include dizziness and somnolence.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Primary brain tumors or symptomatic brain metastases.
2. Unable to swallow food or medication capsules.
3. Patients with oral mucositis or oral fungal infection causing anorexia or impairing taste.
4. Have a disorder that causes obstruction of the gastrointestinal tract or limits the absorption of calories such as bowel obstruction or celiac disease.
5. Receiving tube feedings or parenteral nutrition.
6. Be on, been on within 4 weeks prior to enrollment, or expected to be on medications that have the potential to affect anorexia or caloric intake. Examples of such medications include any synthetic or natural cannabinoid (inhaled or administered by any other route) and megestrol.
7. Corticosteroids are allowed if on a stable or tapering dose for 2 weeks prior to enrollment. Patients taking inhaled corticosteroids are permitted.
8. Current illicit drug use or recreational or medicinal use of cannabinoids.
9. Known hypersensitivity to ART27.13 or any of its excipients. A list of ingredients of ART27.13 capsules will be provided to sites prior to the start of Stage 1 of the protocol. Prior to the start of Stage 2, the list of ingredients will be provided for placebo.
10. Pregnant or breast feeding.
11. Clinically significant depression requiring current use of antidepressant medications.
12. Condition other than cancer that could cause anorexia and/or weight loss such as AIDS, chronic obstructive pulmonary disease, chronic kidney disease, heart failure, or pathological

eating disorder.
13. Uncontrolled, intercurrent illness including, but not limited to, ongoing or active infection requiring intravenous (IV) antibiotics & psychiatric illness/social situations that would limit compliance with study requirements.
14. Major surgery within 2 weeks prior to enrollment.
15. Any comorbid condition that confounds the ability to interpret data from the study as judged by the Investigator or Medical Monitor.
16. Known human immunodeficiency virus infection, acute or chronic hepatitis B, or acute hepatitis C infection.
17. Clinically significant ascites requiring or expected to require paracentesis.
18. Corrected QT intervals (QTc) intervals calculated according to Fridericia's formula (QTcF) >480 ms.
19. Anticipated need for anti-cancer therapy from 2 weeks prior to enrollment and 12 weeks after the first dose of ART27.13 or in Stage 2 ART27.13/placebo. (Continued use of current daily-dose anti-cancer therapy is allowed.)
20. Investigational agent within 4 weeks prior to enrollment or expected need for an investigational agent for 12 weeks after the first dose of ART27.13 or in Stage 2 placebo.
21. Receiving radiotherapy within 2 weeks dating back from enrollment or anticipated to need radiotherapy within 12 weeks of enrollment. Short term palliative radiation treatment involving a local lesion is allowed.

Date of first enrolment
23/03/2021

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
United Kingdom

England

Scotland

Ireland

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh
United Kingdom
EH4 2XU

Study participating centre

The Royal Marsden Hospital (london)
Fulham Road
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Study participating centre
The Royal Marsden Hospital (surrey)
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SM2 5PT

Study participating centre
St James's University Hospital
Gledow Wing
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Study participating centre
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Little Baldon
Oxford
United Kingdom
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Study participating centre
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United Kingdom
G75 8RG

Sponsor information

Organisation
Artelo Biosciences Ltd.

Funder(s)

Funder type
Industry

Funder Name
Artelo Biosciences Ltd.

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes