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A healthy volunteer imaging study to test two new tablet formulations designed to release in the duodenum (the first part of the small intestine)

Submission date 10/03/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol
Registration date 13/03/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 02/04/2026	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study will test two new tablet formulations that are designed to release their contents in the first part of the small intestine (the duodenum). Delivering medicines to this area of the bowel may help with how some drugs are absorbed. The tablets used in this study are placebo and do not contain any active medicine. The placebo tablets will contain a small amount of radiation so that their passage through the stomach and the small intestine can be tracked using a type of medical imaging called gamma scintigraphy. The aim of the study is to test how the two new tablet formulations behave, how quickly they leave the stomach, and where and when they release their contents.

Who can participate?
The study will involve up to 8 adult healthy volunteers, aged 18 years or over. Both men and women can participate.

What does the study involve?
Participants will be required to attend five visits at the BDD clinical trial site at Glasgow Royal Infirmary, with their participation in the study lasting between 3 and 7 weeks in total.
Prior to being dosed with the study treatments, participants will be administered a radiolabelled liquid to allow researchers to visualise their individual gastrointestinal tract anatomy.
During the study the participants will receive two different placebo tablets on separate visits:
• Treatment A: One radiolabelled placebo P1 (Prototype 1) tablet
• Treatment B: One radiolabelled placebo P2 (Prototype 2) tablet

After taking the tablet, the participants will undergo scintigraphic imaging so that the passage of the tablets through the stomach and small intestine can be studied.

What are the possible benefits and risks of participating?
There are no direct benefits to taking part in the study, however the results obtained could be

important for the development of medicinal products which will benefit others. Participants will receive a small exposure to radiation. The radiation dose is low and similar to that used in routine medical imaging procedures.

Where is the study run from?
BDD Pharma

When is the study starting and how long is it expected to run for?
The study is expected to run between April and June 2026.

Who is funding the study?
Scottish Enterprise Grant Award Scheme (Small R&D)

Who is the main contact?
Dr Ewen Brennan, ewen.brennan@bddpharma.com

Contact information

Type(s)
Principal investigator, Public, Scientific

Contact name
Dr Ewen Brennan

ORCID ID
https://orcid.org/0000-0003-2132-5157

Contact details
BDD Pharma Ltd
Bio-Imaging Centre
Within Glasgow Royal Infirmary
84 Castle Street
Glasgow
United Kingdom
G4 0SF
+44 141 552 8791
ewen.brennan@bddpharma.com

Type(s)
Public

Contact name
Ms Alison McColl

Contact details
BDD Pharma Ltd
Bio-Imaging Centre
Within Glasgow Royal Infirmary
84 Castle Street
Glasgow
United Kingdom

G4 0SF
+44 141 552 8791
cro@bddpharma.com

Additional identifiers

Protocol number
BDD25432

Integrated Research Application System (IRAS)
366901

Study information

Scientific Title
A proof-of-concept, open-label, two-arm scintigraphic crossover study in healthy adult volunteers to investigate the in vivo performance of two novel orally administered duodenal targeted drug-delivery formulations

Study objectives
1. To characterise and compare gastric emptying and the timing and anatomical site of release of the two radiolabelled drug-delivery systems (Treatment A and Treatment B) using gamma scintigraphy in healthy adult participants.
2. To evaluate the safety and tolerability of Treatment A and B.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/02/2026, South West - Cornwall & Plymouth Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8000; cornwallandplymouth.rec@hra.nhs.uk), ref: 26/SW/0006

Primary study design
Observational

Secondary study design
Feasibility/Pilot study

Study type(s)

Health condition(s) or problem(s) studied
Duodenal drug delivery

Interventions
This is a non-CTIMP single centre, proof of concept, open-label, two arm, crossover study in up to 8 healthy male and female adult volunteers. This study will evaluate two novel drug delivery systems targeting duodenal drug release.

All participants will report to the Bio-Imaging Centre for all study procedures.

The following treatments will be dosed during the study:
• Treatment A: One radiolabelled placebo P1 (Prototype 1) tablet
• Treatment B: One radiolabelled placebo P2 (Prototype 2) tablet

Participants will attend the centre on up to 5 occasions: a screening visit, 3 assessment visits and a follow up visit.
AV1 will take place within 28 days of the screening visit. All three assessment visits will be separated by at least 3 days. A follow-up visit will be conducted within 14 days after AV3.

All potential participants will give informed consent prior to the examination at the screening visit. The screening visit will last approximately 45 minutes and will comprise collecting information on demographics, medical history, and medication history. A physical examination, BMI calculation, vital signs check, and ECG will also be performed.
Blood and urine samples will be taken for routine tests and urine samples will be further tested for recreational drug use. A breath alcohol test will be performed. Tests may be repeated at the discretion of the medic.

At AV1, a radiolabelled liquid will be administered to each individual participant. Immediately afterwards, continuous images will be taken for approximately 20 minutes using a gamma camera. Following this initial period an image will be taken every 5 minutes for up to 2 hours. Each image will take around 25 seconds to capture. This will produce a visualisation of the participant's gastrointestinal tract anatomy to be used when analysing images captured at the other assessment visits.

At AV2 participants will be dosed with Treatment A and at AV3 participants will be dosed with Treatment B. After dosing at AV2 and AV3 an image will be taken every 5 minutes for up to 4 hours. Each image will take around 25 seconds to capture. Imaging may finish earlier if the required images are obtained sooner, as determined by BDD site staff.

Intervention Type
Mixed

Primary outcome(s)
1. Time and site of onset of radiolabel release measured using scintigraphic imaging at 5 minute intervals for up to 4 hours. Time will be recorded as the mid-point time between the image at which the endpoint is first observed and the previous image.

2. Time and site of completion of radiolabel release measured using scintigraphic imaging at 5 minute intervals for up to 4 hours. Time will be recorded as the mid-point time between the image at which the endpoint is first observed and the previous image.

3. Gastric emptying time of the tablet(s) measured using scintigraphic imaging at 5 minute intervals for up to 4 hours. Time will be recorded as the mid-point time between the image at which the endpoint is first observed and the previous image.

Key secondary outcome(s))
1. Number of treatment emergent and serious adverse events reported following dosing measured using Adverse Event checks at hourly intervals until the participant departs from site

Completion date
31/05/2026

Eligibility

Key inclusion criteria

1. Aged at least 18 years
2. BMI between 18 and 32 kg/m², inclusive.
3. Understands and is willing, able, and likely to comply with all study procedures and restrictions.
4. Demonstrates understanding of the study and willingness to participate as evidenced by voluntary written informed consent (signed and dated) obtained before any trial-related activities.
5. Healthy (as determined by the PI or medically qualified designee) with no clinically significant and/or relevant abnormalities of medical history or prior to dosing evaluations, including physical examination, vital signs, ECG and screening clinical laboratory results. A participant with a clinical abnormality or laboratory parameter(s) which is/are not specifically listed in the inclusion or exclusion criteria, outside the reference range for the population being studied may be included only if the Investigator judges and documents that the finding is unlikely to introduce additional risk factors and will not interfere with the study procedures.
6. Family Planning

Male Participants:

A male participant is eligible to participate if during the study intervention period and for at least 90 days after the last dose of study intervention:

a) They agree to refrain from donating sperm PLUS, either:

b) Are abstinent from heterosexual intercourse as their preferred and usual lifestyle (abstinent on a long term and persistent basis) and agree to remain abstinent OR

c) Agree to use a male condom in addition to their female partner using an additional highly effective contraceptive method with a failure rate of < 1% per year when having sexual intercourse with a woman of childbearing potential who is not currently pregnant

Female Participants:

A female participant is eligible to participate if during the study intervention and for at least until the follow up visit of the study:

a) She is not pregnant or breastfeeding or expressing milk for human consumption AND

b) She agrees to refrain from egg donation PLUS, either:

c) She is of non-childbearing potential (WONCBP) as per CTCG definition OR

d) Agrees to use a highly effective form of birth control preferably with low user dependency if sexually active with a fertile male partner

Healthy volunteers allowed

Yes

Age group

Mixed

Lower age limit

18 years

Upper age limit

110 years

Sex

All

Total final enrolment
0

Key exclusion criteria
1.Medical History
1.1. Current or recurrent disease / condition that, in the opinion of the PI or medically qualified designee responsible, could affect study conduct; the safety of the participant as a result of participation; and/or the ability of the participant to complete the study or laboratory assessments. For example: hepatic disorders, renal insufficiency, congestive heart failure, conditions known to impact gastric emptying such as migraine or diabetes mellitus and relevant non self limiting GI disorders.
1.2. Current or relevant previous history of severe or unstable psychiatric illness, that may require treatment or make the participant unlikely to fully complete the study, or that presents undue risk from the study medication or procedures.
1.3. History of previous surgical intervention which could affect GI transit and/or function for example gastric surgery, vagotomy or known adhesions with previous obstructive symptoms.
1.4.Haematological, biochemical or virology blood test at screening outside normal ranges and deemed clinically significant by the PI or medically qualified designee.
1.5.As a result of a physical examination or screening investigations available prior to dosing evaluations, the PI or medically qualified designee/physician responsible considers the volunteer unfit for the study.
1.6. Measured body temperature >38°C (at screening or assessment visits).
2. Medications
2.1. Participant is scheduled to take prescribed medication within 14 days (or 5 half-lives – whichever is longer) prior to the first or any subsequent assessment visit which, in the opinion of the PI or medically qualified designee responsible, will interfere with the study procedures (or has the potential to affect gastric emptying and/or gut transit) or compromise safety.
2.2. Participant is scheduled to take over the counter (OTC) medication, including vitamins, pro and prebiotics and natural or herbal remedies, within 48 hours prior to the first or any subsequent assessment visit unless approved by the PI or medically qualified designee.
3. Alcohol/Substance Abuse
3.1. Recent history (within the last year) of alcohol or other substance abuse in the opinion of the investigator (including alcohol and marijuana) within the last 2 years prior to informed consent, or a positive urinary drugs of abuse test at any of the defined points in the protocol.
3.2. Participant has an average weekly alcohol intake of greater than 14 units.
3.3. Participant has a positive breath alcohol test at screening or prior to dosing evaluation. (breath testing may be repeated once at investigator discretion within a 5 minute window of first test)
4. Smoking
4.1. Participant is currently a smoker or user of nicotine-containing products.
4.2. Participant has a positive urine cotinine test at screening or prior to dosing evaluation.
5. Allergy/Intolerance: Participant has a history of allergy to any component of the dosage form or any other allergy, which, in the opinion of the PI or medically qualified designee responsible, contraindicates their participation.
6. Clinical Studies
6.1. Participation in another clinical study (inclusive of the final post-study examination) of an investigational drug within the 12 weeks before screening visit, or five elimination half-lives of the previous study drug, whichever is longer.
6.2. Participant whose participation in this study will result in a participation in more than four studies over a twelve month period.
7. Personnel: An employee of the Sponsor, or study site or members of their immediate family.

8. Radiation Exposure: Participant has a total dosimetry value which, in the opinion of the PI or medically qualified designee/physician responsible, contraindicates their participation.
9. Family Planning: Male participants who are intending to father a child in the 90 days following the study or are unwilling or unable to follow the precautions outlined in inclusion criteria 6. OR Female participants who are intending to conceive a child during the treatment period or who are unwilling or unable to follow the precautions outlined in inclusion criteria 6.
10. Other: Participant has any non-removable metal objects such as metal plates, screws etc. in their chest or abdominal area which in the opinion of the PI or medically qualified designee could affect the study conduct.

Date of first enrolment
13/04/2026

Date of final enrolment
22/05/2026

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
BDD Pharma
Bio-Imaging Centre
Within Glasgow Royal Infirmary
84 Castle Street
Glasgow
Scotland
G4 0SF

Sponsor information

Organisation
BDD Pharma Ltd

Funder(s)

Funder type

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	17/02/2026	12/03/2026	No	Yes