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Oral delivery of a vitamin formulation to the colon

Submission date 17/01/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/01/2024	**Overall study status** Completed	
Last Edited 30/05/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
We all have a population of “friendly bacteria” living in our intestines; this is called the gut microbiome. Studies have shown that disturbances in our gut microbiome are associated with several diseases including heart disease and inflammation. By delivering vitamins to the colon and avoiding their absorption earlier in the gastrointestinal tract they are available to the colonic microbiome and can help to maintain a healthy colonic bacteria population.

Who can participate?
Healthy male and female volunteers aged 18-65 years

What does the study involve?
One treatment will be assessed in this study:
Treatment A: Radiolabelled colon targeted vitamin tablet Vitamin formulation containing: Vitamin C (220mg), Vitamin B2 (12mg), Vitamin B6 (2.5mg), Vitamin B3 (5.5mg), Vitamin B5 (6.7 mg), Vitamin B9 (0.5mg)

What are the possible benefits and risks of participating?
There are no direct benefits to participants in taking part in this study.
All materials used in the tablet formulation are standard pharmaceutical ingredients which are generally regarded as safe. These materials will be incorporated in quantities usually found in pharmaceutical formulations.
The safety of vitamins is well established, and several marketed products are available.

Where is the study run from?
BDD Pharma Ltd (UK)

When is the study starting and how long is it expected to run for?
November 2023 to August 2024

Who is funding the study?
The University of Applied Sciences and Arts, Northwestern Switzerland (FHNW)

Who is the main contact?
Lyn Corry, lyn.corry@bddpharma.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
332044

Protocol serial number
BDD22329

Study information

Scientific Title
A proof of concept scintigraphic study to investigate the in vivo performance of an orally delivered colon targeted vitamin formulation in healthy volunteers

Study objectives
Assess the localisation of release for the colon-targeted formulation.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 21/09/2023, West of Scotland REC 5 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 (0)141 314 0213; WoSREC5@ggc.scot.nhs.uk), ref: 23/WS/0127

Primary study design
Interventional

Study design
Open-label single-arm scintigraphic study

Study type(s)
Other

Health condition(s) or problem(s) studied
Oral delivery of vitamin formulation to the colon

Interventions
Treatment A: Colon Targeted Vitamin tablet containing Vitamin C (220mg), Vitamin B2 (12mg), Vitamin B6 (2.5mg), Vitamin B3 (5.5mg), Vitamin B5 (6.7mg), Vitamin B9 (10%)
The intervention was 1 day and the follow up took place within 1 week.

Intervention Type
Supplement

Primary outcome(s)
Site and time of onset of disintegration of the novel vitamin tablet formulation using gamma scintigraphy. Imaging carried out every 15 minutes until a maximum of 14 h post dose.

Key secondary outcome(s)
1. Safety and tolerability of the novel vitamin tablet formulation:
1.1. Safety bloods and urinalysis will be checked at screening and follow up
1.2. Vital signs will be checked at screening, assessment visit and follow up
1.3. Hourly adverse events checks will be conducted from dosing until completion of the assessment visit
2. Gastrointestinal transit parameters of the novel vitamin tablet formulation using gamma scintigraphy. Imaging carried out every 15 minutes until a maximum of 14 h post dose
3. To assess site and time of complete disintegration of the novel vitamin tablet formulation using gamma scintigraphy. Imaging carried out every 15 minutes until a maximum of 14 h post dose.

Completion date
02/08/2024

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years inclusive.
2.1. BMI between 18 and 32 kg/m², inclusive.
2.2. Body weight ≥50 kg

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, in consultation with the Sponsor if required, judges and documents that the finding is unlikely to introduce additional risk factors and will not interfere with the study procedures.
6. Family Planning:
Females must be the following:
Compliant with highly effective methods of contraception as described in section 10.4 (Appendix 4) if they have a fertile male partner.
OR
Of non-reproductive potential defined as:
Pre-menopausal females with one of the following:
Documented tubal ligation.
Documented hysteroscopic tubal occlusion procedure with follow-up confirmation of bilateral tubal occlusion
Hysterectomy
Documented Bilateral Oophorectomy
Documented Postmenopausal defined as 12 months of spontaneous amenorrhea
Partners of male participants of childbearing potential or must be compliant with highly effective methods of contraception

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
12

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 or biochemical blood test at screening or repeat eligibility testing outside normal ranges and deemed clinically significant by the PI or medically qualified designee. Note: In case of abnormal laboratory values that could indicate a temporary condition, the test can be performed again once before enrolment.
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 at assessment visit
2. Medications
2.1. Participant is scheduled to take prescribed non-permitted 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.
3.2. Participant has an average weekly alcohol intake of greater than 14 units.
3.3. Participant has positive urine drugs of abuse test at screening or prior to dosing evaluation.
3.4. Participant has a positive breath alcohol test at screening or prior to dosing evaluation.
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
5.1. 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.
5.2. Participant has an allergy to any of the contents of the standardised meals.
5.3. Participant is vegetarian or vegan.
6. Clinical Studies
6.1. Participation in another clinical study with an investigational drug (inclusive of final post-study examination) or receipt 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
7.1. An employee of the Sponsor, or study site or members of their immediate family.
8. Radiation Exposure

8.1. 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
9.1. Female participants who are currently pregnant
9.2. Female participants who are intending to conceive a child during the study or male participants who are intending to father/conceive a child in the 90 days following the study or any participant unwilling or unable to follow the precautions outlined in inclusion criteria 6.
10. Breastfeeding
Female participants who are breastfeeding or expressing milk for human consumption
11. 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
16/11/2023

Date of final enrolment
14/02/2024

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
BDD Pharma Ltd
Bio-Imaging Centre
Basement Medical Block
Within Glasgow Royal Infirmary
84 Castle Street
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United Kingdom
G4 0SF

Sponsor information

Organisation
BDD Pharma Ltd

Funder(s)

Funder type
University/education

Funder Name
University of Applied Sciences Northwestern Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made 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?
Basic results		30/05/2025	30/05/2025	No	No