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A study comparing the bioavailability of a taste-masked delafloxacin powder for oral suspension with the delafloxacin tablet in healthy adults

Submission date 03/05/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 13/05/2024	**Overall study status** Deferred	
Last Edited 21/05/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The Sponsor is developing a new test medicine recipe of an approved drug called delafloxacin to treat community acquired bacterial pneumonia in paediatric patients. Bacterial infections have increased in hospital and community settings, and other current treatments have begun to be ineffective. Delafloxacin remains effective in treating bacterial infections in adults. However, as the medicine is available only as tablets or intravenous, the Sponsor is developing a liquid form that will be easier for children to swallow. This healthy volunteer study aims to answer these questions:

• How much test medicine gets into the bloodstream and how quickly does the body get rid of it?
• When the test medicine is given as the new liquid and the current tablet form, how do blood levels of the test medicine compare?
• Optionally, does food affect how the test medicine gets into the bloodstream?
• To assess the taste of the new liquid test medicine

Who can participate?
This study will take place at one non-NHS site, enrolling up to 16 male and non-pregnant, non-lactating female volunteers aged between 18-55.

What does the study involve?
Volunteers will take part in up to 4 study periods. In Periods 1 and 2, volunteers will receive a single 450 mg dose of the new liquid formulation of the test medicine and a single 450 mg dose of the reference tablet; the order in which they will take these is randomised. In Period 3 and optional Period 4, they will receive single doses up to 600 mg of the new liquid formulation of the test medicine in either the fasted state (after not eating for at least 10 hours), or following a high-fat breakfast. Volunteers will be discharged from the study once they have completed the follow up phone call or unscheduled follow up visit in their final study period.

What are the possible risks and benefits of participating?
1. As this is a Phase I study, the population is healthy volunteers. It is considered that the risk /benefit evaluation in this study supports the use of healthy volunteers.
2. There is always a risk that the stipend in healthy volunteer studies could represent coercion. The time spent in the clinic, travel, inconvenience and other expenses factor in calculating the stipend. Perception of risk is not considered in this calculation.
3. When investigating new medicines there is always a risk of unexpected side effects and occasionally allergic reactions. Volunteers will be closely monitored during the study.
4. Volunteers may experience side effects from the test medicine in this study. Full information on possible side effects is provided to volunteers in the Participant Information Sheet and Informed Consent Form.
5. There will be an extended period of fasting for the volunteers taking part in this study. To ensure an adequate fluid intake, the volunteers will be allowed as much fluid as needed 1 hour post dose and will be monitored for signs of dehydration and fatigue.
6. Blood samples will be collected during the study. Collection of these samples can cause soreness and bruising of the arms, but these problems usually clear up within a few days to a few weeks.
7. ECG stickers on volunteers' chests and limbs may cause some local irritation and may be uncomfortable to remove but volunteers will be closely monitored to ensure any local irritation does not persist.

Participants will get no medical benefit from taking part in this study. We hope that the development of a treatment for paediatric bacterial infection and community-acquired pneumonia may benefit the population as a whole.

Where is the study run from?
Melinta Subsidiary Corp. (USA)

When is the study starting and how long is it expected to run for?
June 2024 to October 2024

Who is funding the study?
Melinta Subsidiary Corp. (USA)

Who is the main contact?
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT06612255

Integrated Research Application System (IRAS)
1009679

Protocol serial number
Sponsor code: ML-DEL-101-3727-1, Quotient code QSC300553

Study information

Scientific Title
A phase 1, single part, partially randomised, open-label study to evaluate the relative bioavailability of a taste-masked delafloxacin powder for oral suspension with oral delafloxacin tablet reference in healthy subjects

Study objectives
The trial will meet the following primary and secondary objectives:
Primary objective:
1. To determine the relative bioavailability of delafloxacin Powder for Oral Suspension compared to that of oral delafloxacin Tablet reference.
Secondary objectives:
1. To determine the pharmacokinetics of delafloxacin Powder for Oral Suspension formulation.
2. To determine the relative bioavailability of delafloxacin Powder for Oral Suspension in the fed and fasted state.
3. To provide additional safety and tolerability information for orally administered delafloxacin.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/05/2024, South Central - Berkshire (Bristol REC Centre, Temple Quay House, 2 The Square, Temple Quay, Bristol, BS1 6PN, United Kingdom; +44 (0)207 104 8178; berkshire.rec@hra.nhs.uk), ref: 24/SC/0081

Primary study design
Interventional

Study design
Relative bioavailability study in 16 healthy volunteers

Study type(s)
Other, Safety

Health condition(s) or problem(s) studied
Acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacteria pneumonia (CABP)

Interventions
This is a partially-randomised open-label study. This healthy volunteer study will measure blood levels of a new liquid formulation of the test medicine, and investigate whether the liquid formulation is comparable to the existing tablet formulation when given in the fasted state. Volunteers will receive up to 4 doses of the test medicine; up to 3 doses of the liquid formulation and one dose of the existing tablet formulation, with a minimum washout of 4 days between doses. Up to two doses of the new liquid formulation may be given with food to assess the effect of food on the test medicine. This study will take place at one non-NHS site, enrolling 16 male or non-pregnant, non-lactating females aged between 18 and 55. Volunteers will take part in up to 4 study periods. In Periods 1 and 2 they will receive single 450 mg doses of delafloxacin Tablet and delafloxacin Powder for Oral Suspension, reconstituted with orange flavoured vehicle in the fasted state; the order in which they receive these doses will be randomised. In Period 3 and optional Period 4, they will receive single doses up to 600 mg delafloxacin Powder for Oral Suspension, reconstituted with orange flavoured vehicle in either

the fasted state, or following a high-fat breakfast. Volunteer's blood and urine will be taken throughout the study for analysis of the test medicine and for their safety. Volunteers will be discharged from the study once they have completed the follow up phone call or unscheduled follow up visit in their final study period. Volunteers are expected to be involved in the study for up to 14 weeks from screening to discharge.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
1. Delafloxacin Tablet, 450 mg (trade name: Baxdela, name of active substance: Delafloxacin) 2. Delafloxacin Powder for Oral Suspension, 300–600 mg

Primary outcome(s)
Results of the formal statistical analysis of overall exposure (AUC) for delafloxacin Powder for Oral Suspension compared to oral delafloxacin Tablet reference measured using blood samples taken from Day 1 of Period 1 to Day 3 of the final study period.

Key secondary outcome(s)
1. Pharmacokinetic parameters measured using blood samples taken from Day 1 of Period 1 until Day 3 of the final study period.
2. Results of the formal statistical analysis of overall exposure (AUC) for delafloxacin Powder for Oral Suspension in the fed state compared to the fasted state measured using blood samples taken from Day 1 of Period 1 until Day 3 of the final study period.
3. Safety and tolerability measured using the incidence of adverse events and serious adverse events, and changes from baseline for vital signs, electrocardiograms, physical examinations and laboratory safety tests from Day -1 until discharge from the study.

Completion date
09/09/2024

Eligibility

Key inclusion criteria
1. Must provide written informed consent.
2. Must be willing and able to communicate and participate in the whole study.
3. Aged 18 to 55 years inclusive at the time of signing informed consent.
4. Must agree to adhere to contraception requirements defined in the Clinical Protocol and Participant Information Sheet and Informed Consent Form.
5. Healthy males or non-pregnant, non-lactating healthy females.
6. Body mass index (BMI) of 18.0 to 32.0 kg/m² as measured at screening.
7. Weight ≥50 kg at screening.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
All

Total final enrolment
16

Key exclusion criteria
1. SAR (severe adverse reaction) or serious hypersensitivity to any drug or formulation excipients.
2. Any history of hypersensitivity to delafloxacin or any other fluroquinolones or previous history of tendon disorders related to fluroquinolone administration.
3. Presence or history of clinically significant allergy requiring treatment, as judged by the Investigator. Hay fever is allowed unless it is active.
4. History of clinically significant cardiovascular, renal, hepatic, respiratory, particularly GI disease, especially peptic ulceration, GI bleeding, ulcerative colitis, Crohn's Disease or Irritable Bowel Syndrome, and neurological or psychiatric disorders.
5. Subjects with a history of cholecystectomy or gallstones.
6. Acute diarrhoea or constipation in the 7 days before the predicted Day 1. If screening occurs >7 days before the Day 1, this criterion will be determined on Day 1. Diarrhoea will be defined as the passage of liquid faeces and/or a stool frequency of greater than 3 times per day. Constipation will be defined as a failure to open the bowels more frequently than every other day.
7. Subject has a medical condition that may adversely affect taste or smell activity including but not limited to mouth ulcers, significant gum disease, and respiratory and/or sinus infection or cold.
8. Subject does not agree to the consumption of, or has any known allergies to, the formulation excipients.
9. Subjects who do not have suitable veins for multiple venepunctures/cannulation as assessed by the Investigator or delegate at screening or admission.
10. Clinically significant abnormal clinical chemistry, haematology or urinalysis as judged by the Investigator. Subjects with Gilbert's Syndrome are not allowed.
11. Positive hepatitis B surface antigen (HBsAg), hepatitis C virus antibody (HCV Ab), or human immunodeficiency virus (HIV) 1 and 2 antibody results.
12. Females who are pregnant or lactating (all female subjects must have a negative highly sensitive urine or serum pregnancy test).
13. Subjects who have received any IMP in a clinical research study within the 90 days of the planned first dose date, or less than 5 elimination half-lives prior to the planned first dose date, whichever is longer.
14. Donation of blood or plasma within the previous 3 months or loss of greater than 400 mL of blood.

15. Subjects who are taking, or have taken, any prescribed or over-the-counter drug or herbal remedies (other than up to 4 g of paracetamol per day, hormonal contraception, or HRT) in the 14 days before the first dose of IMP. Exceptions may apply, as determined by the Investigator, if each of the following criteria are met: medication with a short half-life if the washout is such that no pharmacodynamic activity is expected by the time of dosing with IMP; and if the use of medication does not jeopardise the safety of the trial subject; and if the use of medication is not considered to interfere with the objectives of the study.
16. Subjects who are taking, or have taken, any antibacterial medications, antacids, medications containing multivalent cations or metal cations, multivitamin preparations containing zinc or iron, or didanosine buffered tablets within 14 days prior to the first dose of IMP.
17. Subjects who have had a COVID-19 vaccine within 2 days (48 hours) prior to admission.
18. History of any drug or alcohol abuse in the past 2 years.
19. Regular alcohol consumption in males >21 units per week and in females >14 units per week (1 unit = ½ pint beer, or a 25 mL shot of 40% spirit, 1.5 to 2 units = 125 mL glass of wine, depending on type).
20. A confirmed positive alcohol breath test at screening or admission.
21. Current smokers and those who have smoked within the last 12 months.
22. Current users of e-cigarettes and nicotine replacement products and those who have used these products within the last 12 months.
23. A confirmed breath carbon monoxide reading of greater than 10 ppm at screening or admission.
24. Confirmed positive drugs of abuse test result at screening or admission.
25. Male subjects with pregnant or lactating partners.
26. Subjects who are, or are immediate family members of, a study site or Sponsor employee.
27. Subjects who do not agree to eat a high-fat breakfast.
28. Failure to satisfy the Investigator of fitness to participate for any other reason.

Date of first enrolment
03/06/2024

Date of final enrolment
01/10/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Quotient Sciences Limited
Mere Way
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Sponsor information

Organisation
Melinta Subsidiary Corp. (USA)

Funder(s)

Funder type
Industry

Funder Name
Melinta Subsidiary Corp. (USA)

Funder Name
Biomedical Advanced Research and Development Authority

Alternative Name(s)
Center for the Biomedical Advanced Research and Development Authority, BARDA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to commercial sensitivity and the negligible benefit to the public of results of non-therapeutic clinical trials.

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	Participant information sheet	11/11/2025	11/11/2025	No	Yes