ISRCTN12656966 https://doi.org/10.1186/ISRCTN12656966

A study in healthy volunteers to investigate how the test medicine Empli-03 buccal tablet is taken up, broken down and removed by the body

Submission date
15/08/2022

Recruitment status
No longer recruiting

Registration date
15/08/2022

Overall study status
Completed

Last Edited
11/04/2025

Condition category
Signs and Symptoms

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The Sponsor is developing a new formulation, Empli-03, of an already approved active ingredient, buprenorphine, for the potential treatment of chronic pain. Empli-03 is a buccal tablet, which means it is administered orally by placing it between the gum and the upper lip. This single-period healthy volunteer study will try to identify how the test medicine is taken up, broken down and removed by the body. The safety and tolerability of the test medicine will also be investigated.

Who can participate?
Healthy males or non-pregnant, non-lactating healthy females aged 18 to 55 years.

What does the study involve?
The study consists of one part, involving a single cohort of 12 volunteers. Volunteers receive a single dose of the test medicine on the morning of Day 1 and will be required to hold the tablet under the upper lip for approximately 6 hours. Naltrexone hydrochloride is given in this study to help minimise any side effects from buprenorphine (the active ingredient in the test medicine), on Day -1, and on Day 1, approximately 1 hour before and approximately 12 hours after the dose of the test medicine. Volunteers enter the unit on Day -1 and are discharged on Day 4. Volunteers will receive a follow-up phone call, between Day 8 and 10. Volunteers' blood and urine will be taken throughout the study for analysis of the test medicine and for their safety. Volunteers are expected to be involved in this study for approximately 6 weeks from screening to the follow-up call.

What are the possible risks and benefits of participating?
Participants get no medical benefit from taking part in the study. However, the development of a treatment for chronic pain may benefit the population as a whole. It is considered that the risk /benefit evaluation in this study supports the use of healthy volunteers. Full information on possible side effects is provided to volunteers in the Participant Information Sheet and Informed

Consent Form. Volunteers are closely monitored during the study and safety assessments are performed regularly.

Where is the study run from?
Emplicure AB (Sweden)

When is the study starting and how long is it expected to run for?
October 2022 to November 2022

Who is funding the study?
Emplicure AB

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1005812

Protocol serial number
Sponsor code: Empli-03

Study information

Scientific Title
A single-period open-label study designed to evaluate the pharmacokinetics of Empli-03 buccal tablet formulation in naltrexone-blocked healthy subjects

Study objectives
The trial will meet the following primary and secondary objectives:

Primary Objective:
To determine the PK of buprenorphine and norbuprenorphine following administration of an Empli-03 buccal tablet formulation in naltrexone-blocked healthy volunteers.

Secondary Objective:
To provide additional safety and tolerability information for an Empli-03 buccal tablet formulation in naltrexone-blocked healthy volunteers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/09/2022, London Harrow REC (Bristol HRA Centre, Temple Quay House, 2 The Square, Temple Quay, Bristol, BS1 6PN, United Kingdom; harrow.rec@hra.nhs.uk), ref: 22/FT/105

Study design
Pharmacokinetic trial in healthy volunteers

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Chronic pain

Interventions
Each participant will receive a single buccal dose of Empli-03 Buccal Tablet, 0.8 mg on one occasion after receiving two 50 mg oral doses of naltrexone hydrochloride, and before a third 50 mg oral dose of naltrexone hydrochloride.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Empli-03 (INN: buprenorphine hydrochloride)

Primary outcome(s)
Pharmacokinetic parameters including, but not limited to Cmax, AUC(0-last), and AUC(0-inf) for buprenorphine and norbuprenorphine measured using blood samples taken at multiple timepoints up to 72 h post dose

Key secondary outcome(s))
Additional safety and tolerability information for the test product: adverse events (AEs), vital signs, ECGs, physical examinations, local tolerance, and safety laboratory tests from the time of signing the informed consent form up until discharge from the study

Completion date
02/11/2022

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. Must understand and agree to keep the IMP in place for the full 6 h of dosing
4. Aged 18 to 55 years inclusive at the time of signing informed consent
5. Must agree to adhere to the contraception requirements defined in the clinical protocol
6. Healthy males or non-pregnant, non-lactating healthy females
7. Body mass index (BMI) of 18.0 to 30.0 kg/m2, inclusive, as measured at screening
8. 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
12

Key exclusion criteria
1. Serious adverse reaction or serious hypersensitivity to any drug or formulation excipients.
2. Presence or history of clinically significant allergy requiring treatment, as judged by the investigator. Hay fever is allowed unless it is active.
3. History of clinically significant cardiovascular, renal, hepatic, dermatological, chronic respiratory or gastrointestinal disease (cholecystectomy is allowed), neurological or psychiatric disorder, as judged by the investigator.
4. Subject has a medical condition that may adversely affect taste or smell activity.
5. Subject has a medical condition that causes chronic pain or requires regular pain management with medication.
6. Subjects who do not have suitable veins for multiple venepunctures/cannulation as assessed by the investigator or delegate at screening.
7. Evidence of poor dental status, e.g. (but not limited to) poor oral hygiene, local irritation or ulcers at site of administration, or long-term dry mouth, as confirmed by an oral examination at screening and admission.
8. Evidence of current SARS-CoV-2 infection within 28 days of IMP administration.
9. Clinically significant abnormal clinical chemistry, haematology or urinalysis as judged by the investigator. Subjects with Gilbert's Syndrome are allowed.
10. Positive hepatitis B surface antigen (HBsAg), hepatitis C virus antibody (HCV Ab) or human immunodeficiency virus (HIV) 1 and 2 antibody results.
11. Females who are pregnant or lactating.
12. Subjects who have received any IMP in a clinical research study within the 90 days prior to Day 1, or less than 5 elimination half-lives prior to Day 1, whichever is longer.
13. Donation of blood or plasma within the previous 3 months or loss of greater than 400 mL of blood.
14. Subjects who report to have received buprenorphine within the past 30 days, at the discretion of the Investigator.
15. Subjects who are taking, or have taken, any prescribed or over-the-counter drug or vitamin /herbal remedies (other than up to 4 g of paracetamol per day only on occasion with a maximum of 2-3 days use in a row, HRT and contraceptive pill/hormonal contraception) in the 14 days before IMP administration. COVID-19 vaccines are accepted concomitant medications.
16. History of any drug or alcohol abuse.
17. Regular alcohol consumption in males >21 units per week and 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).
18. A confirmed positive alcohol breath test at screening or admission.
19. Current smokers and those who have smoked within the last 12 months. A confirmed breath carbon monoxide reading of greater than 10 ppm at screening or admission.
20. Current users of e-cigarettes, nicotine replacement products and nicotine containing products and those who have used these products within the last 12 months.
21. Confirmed positive drugs of abuse test result.
22. Opioid usage during the last year, or long-term usage (>4 weeks), at the discretion of the Investigator.
23. Subjects who are, or are immediate family members of, a study site or sponsor employee.
24. Failure to satisfy the investigator of fitness to participate for any other reason.

Date of first enrolment
03/10/2022

Date of final enrolment
02/11/2022

Locations

Countries of recruitment
United Kingdom

England

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Sponsor information

Organisation
Emplicure AB

Funder(s)

Funder type
Industry

Funder Name
Emplicure AB

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are not expected to be made available because of their high commercial sensitivity and the negligible benefit to the public of publication of results of nontherapeutic clinical trials.

IPD sharing plan summary

Not expected to be made available