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An open-label mass balance study of [14C] EIK1001 in healthy male subjects

Submission date 07/05/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/05/2025	**Overall study status** Completed	
Last Edited 12/05/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims

The Sponsor is developing the test medicine, EIK1001, as a potential treatment for cancer using the body's immune system. Similar anticancer treatments aim to block checkpoints that regulate the immune system, leading to the immune system attacking tumours in the body. However, these current therapies do not work for everyone, and more than half of patients eventually experience cancer progression while on treatment.

The test medicine helps cells and proteins associated with the immune system trigger a more effective response against tumours and can be used alongside current anticancer treatments. This kind of treatment can lead to the immune system remembering how to target the cancer cells and provide a long-lasting treatment.

The test medicine has already been given to patients with cancer, but no healthy volunteers have received it before.

We'll give healthy volunteers a single dose of test medicine to find out how the body breaks down and gets rid of the test medicine. The test medicine will be 'radiolabelled' – it will contain a small amount of radioactivity - so that we can track it in the body.

In this study in healthy volunteers, we aim to answer these questions:

1. What are the blood levels of the test medicine and how quickly does the body get rid of it?
2. How does the body break down the test medicine, and what is it broken down into?
3. Does the test medicine cause any important side effects?

Who can participate?

Healthy men aged 30-65 years

What does the study involve?

Volunteers will receive a single dose of radiolabelled test medicine by injection into a vein. They' ll stay in the clinic for up to 10 nights, attend 1 outpatient visit, and take up to 6 weeks to finish the study.

We'll collect blood and urine samples to do safety tests. Over a period of at least 9 days, we'll take many blood samples and volunteers will collect all their urine and faeces so that we can measure the amount of test medicine and its breakdown products.

What are the possible benefits and risks of participating?
Benefits:
Participants will get no medical benefit from taking part in this study. We hope that the development of a potential treatment for cancer will be of benefit to patients with this condition.
Risks:
Volunteers may experience side effects from the test medicine. The test medicine is early in development so there is little information about its effects in humans. Additionally, volunteers may experience side effects from the marketed medicines to be administered with the test medicine. Full information on possible side effects is in the Participant Information Sheet and Informed Consent Form. There is always a risk of unexpected side effects or an allergic reaction. To mitigate the risk, we'll ensure that volunteers meet the entry criteria for the study and monitor volunteers closely throughout the study.
Volunteers will be exposed to 0.26 milliSieverts (mSv) of radioactivity during the study, which is equivalent to about 35 days' exposure to average background radiation in the UK (2.7 mSv per year). That amount of radiation poses negligible risk to the volunteers' health.
Our screening tests might be of benefit if we find an important medical problem, but they might reveal something that the volunteer would prefer not to know about. If there are medically important findings in our tests at screening or during the study, we will inform the volunteer's GP.
Volunteers will be confined to the clinic during the study and must make outpatient visits and comply with the lifestyle restrictions described in the PIS-ICF, including periods of fasting from food and drink except water, and short periods during which they'll be allowed no fluids.
The test medicine might harm unborn children, so all volunteers must follow the restrictions on donation of sperm and use acceptable contraception. If a partner of a volunteer becomes pregnant during the study, we would ask permission to follow up on the pregnancy.
Administration of the test medicine into a vein and blood sampling can cause soreness and bruising of the arms, but these problems usually clear up within a few days to a few weeks.
Susceptible volunteers may faint when we take blood samples; volunteers must lie down when we take blood samples to mitigate that risk.
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.
Healthy volunteers will get no medical benefit from the test medicine; however, the aims of the study can be most efficiently met in volunteers with no concurrent medical conditions and who do not need to take concomitant medication that might interfere with the study objectives or increase the risk of the study. The risk/benefit evaluation in this study supports the use of healthy volunteers.
Volunteers will receive payment for participating in the study. There is always a risk that payment could represent coercion. However, payment will be based on committed time, inconvenience, travel and other expenses, not on risk. An ethics committee will review the payment to ensure that it is fair.

Where is the study run from?
Quotient Sciences Limited (UK)

When is the study starting and how long is it expected to run for?
February 2025 to November 2025

Who is funding the study?
Eikon Therapeutics, Inc. (USA)

Who is the main contact?
Dr Harry Raftopoulos, raftopoulosh@eikontx.com
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Contact information

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Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
1010478

Protocol serial number
Study Code: EIK1001-007, Quotient Code: QSC302234

Study information

Scientific Title
An open-label, single-dose, single-period study designed to assess the mass balance recovery, metabolite profile and metabolite identification of [14C]EIK1001 administered intravenously in healthy male subjects

Study objectives
Primary Objectives:
1. To determine the routes and rates of excretion of [14C]EIK1001-related radioactivity, including mass balance of total drug-related radioactivity in urine and faeces, following administration of a single IV dose of [14C]EIK1001 in healthy subjects
2. To determine the pharmacokinetics (PK) of total radioactivity in whole blood and plasma following a single IV dose of [14C]EIK1001 in healthy subjects
3. To characterise the single-dose plasma and urine PK of EIK1001 following a single IV dose of [14C]EIK1001 in healthy subjects

Secondary Objective:
To evaluate the safety and tolerability of EIK1001 following a single IV dose of [14C]EIK1001 in healthy subjects

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/02/2025, London - Hampstead Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; hampstead.rec@hra.nhs.uk), ref: 24/LO/0746

Primary study design
Interventional

Study design
Healthy volunteer absorption, distribution, metabolism, and excretion (ADME) study

Study type(s)
Other, Safety

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
[14C]EIK1001 single intravenous dose, 30-minute infusion of 0.5 mg [14C]EIK1001 containing not more than (NMT) 2.9 MBq

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
[14C]EIK1001

Primary outcome(s)
1. Route of excretion of [14C]EIK1001 radioactivity as measured by mass balance of total drug-related radioactivity in urine and feces. Mass balance of total drug-related radioactivity in urine and feces following dosage of [14C]EIK1001, as a percentage (%) of the dose administered. [Time Frame: Day 1 to Day 10]

2. Rate of excretion of [14C]EIK1001 radioactivity as measured by mass balance of total drug-related radioactivity in urine and feces. Mass balance of total drug-related radioactivity in urine and feces following dosage of [14C]EIK1001, as a percentage (%) of the dose administered. [Time Frame: Day 1 to Day 10]
3. PK of total radioactivity in whole blood and plasma following a single IV dose of [14C]EIK1001 For total radioactivity in whole blood and plasma, PK parameters include but are not limited to Cmax, Tmax, T1/2, AUC(0-last), AUC(0-inf), Vd, and CL. [Time Frame: Day 1 to Day 10]
4. PK of EIK1001 in plasma and urine following a single IV dose of [14C]EIK1001 in healthy subjects. PK parameters include but are not limited to Cmax, Tmax, T1/2, AUC(0-last), AUC(0-inf), Vd, CL, and CLr for EIK1001 in plasma, and Ae, CumAe, %Ae, and Cum%Ae for EIK1001 in urine. [Time Frame: Day 1 to Day 10]

Key secondary outcome(s)
Safety and tolerability of EIK1001 following a single IV dose of [14C]EIK1001 assessed using data including but not limited to vital signs, ECGs, clinical laboratory safety parameters, adverse event reporting, and physical examination [Time Frame: Day 1 to Day 10]

Completion date
27/11/2025

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 30 to 65 years inclusive at the time of signing informed consent
4. Must agree to adhere to the contraception requirements for at least 6 months after dosing
5. Healthy male subjects according to the assessment of the investigator, as based on a complete medical history including a physical examination, vital signs, 12-lead ECG, and laboratory safety tests without any clinically significant abnormalities as available at the time of the assessment
6. BMI of 18.0 kg/m2 to 35.0 kg/m2 as measured at screening
7. Weight ≥50 kg at screening
8. BSA of 1.50 m2 to 2.50 m2 as measured at screening (using Mosteller’s simplified calculation)
9. Must have regular bowel movements (i.e. average stool production of ≥1 and ≤3 stools per day)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
30 Years

Upper age limit

65 Years

Sex
Male

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. Known allergy/intolerance to corticosteroids or antihistamines.
4. Known history of galactose intolerance, total lactase deficiency or glucose galactose malabsorption.
5. Known hypotensive reaction to any previous vaccine administration.
6. History of clinically significant cardiovascular, renal, hepatic, dermatological, chronic respiratory or GI disease, neurological or psychiatric disorder, as judged by the investigator.
7. Subjects with diabetes mellitus.
8. Subjects with any predisposition for urinary retention (e.g. spinal cord lesion, prostatic hyperplasia) (as cetirizine hydrochloride may increase the risk of urinary retention).
9. Subjects who are at risk of convulsions (e.g. history of seizure activity outside of the setting of infantile febrile convulsions).
10. Subjects with a history of any autoimmune diseases (e.g. lupus, rheumatoid arthritis).
11. Subjects who do not have suitable veins for multiple venipunctures/cannulation as assessed by the investigator or delegate at screening.
12. Clinically significant abnormal clinical chemistry, hematology or urinalysis as judged by the investigator. Subjects with Gilbert's Syndrome are not allowed.
13. Positive hepatitis B surface antigen (HBsAg), hepatitis C virus antibody (HCV Ab) or human immunodeficiency virus (HIV) 1 and 2 antibody results.
14. Evidence of renal impairment at screening, as indicated by an estimated creatinine clearance (CrCl) of <80 ml/min using the Cockcroft-Gault equation.
15. 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. Radiation exposure, including that from the present study, excluding background radiation but including diagnostic x-rays and other medical exposures, exceeding 5 mSv in the last 12 months or 10 mSv in the last 5 years. No occupationally exposed worker, as defined in the Ionizing Radiation Regulations 2017, shall participate in the study.
16. Subjects who have been administered IMP in an ADME study in the last 12 months.
17. Donation of blood or plasma within the previous 3 months or loss of greater than 400 ml of blood.
18. Subjects who are taking, or have taken, any prescribed or over-the-counter drugs or herbal remedies (other than up to 4 g of paracetamol per day) in the 14 days before IMP administration. 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 jeopardize the safety of the trial subject; and if the use of medication is not considered to interfere with the objectives of the study.
19. Subjects who have received any vaccine in the 30 days before IMP administration or intend to receive a vaccine within the 14 days after IMP administration.
20. History of any drug or alcohol abuse in the past 2 years (any use of recreational drugs is considered drug abuse when assessing this criterion).
21. Regular alcohol consumption in males >21 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).

22. A confirmed positive alcohol breath test at screening or admission.
23. Current smokers and those who have smoked within the last 12 months.
24. Current users of e-cigarettes and nicotine replacement products and those who have used these products within the last 12 months.
25. A confirmed breath carbon monoxide (CO) reading of greater than 10 ppm at screening or admission.
26. Confirmed positive drugs of abuse test at screening or admission.
27. Subjects with pregnant or lactating partners.
28. Subjects who are, or are immediate family members of, a study site or sponsor employee.
29. Failure to satisfy the investigator of fitness to participate for any other reason.

Date of first enrolment
09/05/2025

Date of final enrolment
12/06/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Quotient Sciences Limited
Mere Way
Ruddington Fields
Ruddington, Nottingham
United Kingdom
NG11 6JS

Sponsor information

Organisation
Eikon Therapeutics, Inc.

Funder(s)

Funder type
Industry

Funder Name
Eikon Therapeutics, Inc.

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 the commercial sensitivity of this Phase I study.

IPD sharing plan summary
Not expected to be made available