

# C34-PEG-4-Chol - a new fusion inhibitor for the treatment of HIV

<b>Submission date</b> 28/01/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/01/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/07/2018	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

HIV (human immunodeficiency virus) is a virus that damages a person's immune system, making them less able to fight infections and disease. There is no cure for the infection, but there are now some very effective treatments, called antiretrovirals, that stop the virus from replicating and therefore help infected people have long and healthy lives. The success of these treatments means that HIV-positive people are now aging. This poses new problems such as heart, kidney, bone and liver diseases which, although associated with ageing, may be more widespread due to the long-term side-effects of anti-HIV drugs. Additionally, drug-drug interactions become increasingly frequent and more complex when treating people who are on treatment for other problems. Therefore, developing new anti-HIV drugs, with less toxicity and likelihood for interactions, is critical. C34-PEG-4-Chol belongs to a family of anti-HIV medications called "fusion inhibitors". C34-PEG-4-Chol is similar to another drug in this family called enfuvirtide. Due to how it is broken down by the body enfuvirtide shows little general toxicity and few drug interactions. However it requires injection under the skin twice daily and injection site reactions are common. C34-PEG-4-Chol is expected to need injecting less frequently resulting in fewer reactions. This study will investigate whether giving this drug to humans is safe.

### Who can participate?

HIV-positive men aged 18-60

### What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 are given C34-PEG-4-Chol. Those in group 2 are given a placebo. Samples from each participant are then collected at various time points. Stage 1 involves giving a single dose, allowing researchers to work out the best dose and how often to give it. Stage 2 involves giving 4 doses then checking how much drug gets into the bloodstream and how much the HIV level drops. Each stage should take about 6 months to complete.

### What are the possible benefits and risks of participating?

There are no specific advantages of taking part in this study. Risks include side effects to C34-PEG4-Chol which may include injection site reactions (redness, swelling, feeling itchy, bruises, hardened skin or bumps, pain, feeling sore or tender), diarrhoea, nausea / vomiting, raised white

blood cell count, pneumonia, feeling weak or tired, headache, feeling dizzy, not being able to sleep, feeling anxious or low in mood, fever, weight loss, poor appetite, pain and feeling numb in hands, feet or legs, swollen glands (lymph nodes). However C34-PEG4-Chol has never been given to humans before so it is possible other unpredictable side effects could occur. As the study involves giving C34-PEG4-Chol without any other anti-HIV drugs, it is possible that HIV resistance to C34-PEG4-Chol could develop. This could also mean that resistance develops to enfuvirtide and any other fusion inhibitor drugs developed in the future. It is possible that if C34-PEG4-Chol were given to a person who was planning to become pregnant with their partner that it might harm an unborn child. Blood tests can sometimes cause bruising and soreness of the arms or, very rarely, a blockage of a vein or a small nerve injury which can cause numbness and pain. Normally these problems disappear with time. Some people may faint while the blood is being drawn.

Where is the study run from?

Imperial College Healthcare NHS Trust (UK)

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

February 2015 to November 2015

Who is funding the study?

Medical Research Council (UK)

Who is the main contact?

Mrs Nicki Doyle

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Nicki Doyle

### Contact details

St Mary's Hospital  
Imperial College Healthcare NHS Trust  
10th Floor QEQM Building Imperial College  
St Mary's Campus  
South Wharf Road  
London  
United Kingdom  
W2 1NY

## Additional identifiers

### EudraCT/CTIS number

2014-002671-28

### IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

17974

## **Study information**

### **Scientific Title**

A phase 1, first in man, study to assess the safety, pharmacokinetic profile and antiretroviral efficacy of C34-PEG-4-Chol, a novel peptide fusion inhibitor for the treatment of HIV infection

### **Study objectives**

The aims of the study are:

1. To assess the safety, pharmacokinetics and pharmacodynamics of C34-PEG4-Chol in HIV-positive individuals.
2. To determine the optimal dose and dosing schedule for C34-PEG4-Chol.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

NRES Committee London - Central, 24/12/2014, ref: 14/LO/2078

### **Study design**

Randomised; Interventional; Design type: Treatment

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

### **Health condition(s) or problem(s) studied**

Topic: Infectious diseases and microbiology; Subtopic: Infection (all Subtopics); Disease: Infectious diseases and microbiology

### **Interventions**

1. C34-PEG4-Chol (Peptivir-H), HIV fusion inhibitor
2. Placebo, sodium chloride 0.9% solution

## **Intervention Type**

Drug

## **Phase**

Phase I

## **Drug/device/biological/vaccine name(s)**

C34-PEG-4-Chol

## **Primary outcome measure**

1. Safety, pharmacokinetic & pharmacodynamic (viral decay - stage 2 only) parameters; Timepoint (s): Stage 1 - up to day 84 post-single dose
2. Stage 2 - follow up duration to be determined from stage 1

## **Secondary outcome measures**

1. Changes in plasma HIV RNA; Timepoint(s): Stage 1 - measured up to day 28 post-single dose
2. Detailed pharmacokinetic profile of C34-PEG4-Chol when administered at different single doses. Timepoint(s): Stage 1 - profile at day 84 post-single dose
3. Detailed pharmacokinetic profile of C34-PEG4-Chol when administered following multiple dosing; Timepoint(s): Stage 2 - profile at final follow up (duration to be determined from stage 1)
4. Emergence of mutations within heptad repeat-1 (HR-1) region of gp41; Timepoint(s): Stage 2 - measured up to 4th follow up visit (duration of follow up to be determined from stage 1)
5. Listing of all adverse events (grade 1 and above); Timepoint(s): Stage 1-up to day 84 post-single dose  
Stage 2-up to final follow up (fu determined from stage 1)

## **Overall study start date**

23/07/2013

## **Completion date**

01/04/2016

# **Eligibility**

## **Key inclusion criteria**

1. The ability to understand and sign a written informed consent form, prior to participation in any screening procedures, and be willing to comply with all study requirements
2. Male
3. Between 18 to 60 years, inclusive
4. Documented HIV-1 infected for  $\geq 6$  months from screening
5. Comorbidities, if present, optimally managed and stable
6. Normal physical examination
7. No clinically significant abnormalities on laboratory screening test
8. BMI 19-28, inclusive
9. Patients who are heterosexually active must agree to use two effective forms of contraception (e.g., condom with spermicide and established hormonal contraception) during heterosexual intercourse, from screening through to completion of the study
10. CD4 count  $\geq 400$  cells/ $\mu$ L at screening

11. Plasma HIV RNA  $\geq 10000$  copies/mL at screening
12. In the opinion of the investigator not likely to require ART in the next 4 months
13. No clinically significant abnormalities on 12-lead ECG

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Male

**Target number of participants**

Planned Sample Size: 42; UK Sample Size: 42; Description: In stage 1 a maximum of 28 participants (20 active, 8 placebo) will be enrolled. In stage 2 a maximum of 14 participants (11 active, 3 placebo) will be enrolled.

**Key exclusion criteria**

1. Any serious or active medical or psychiatric illness which, in the opinion of the investigator, would interfere with patient treatment, assessment, or compliance with the protocol. This would include any active clinically significant renal, cardiac, hepatic, pulmonary, vascular, metabolic (thyroid disorders, adrenal disease) disease immunodeficiency disorders, active infection, or malignancy
2. Participation in an investigational trial involving administration of any investigational compound within 90 days of screening
3. History of alcohol use considered by the investigator to be sufficient to hinder compliance with treatment, follow-up procedures or evaluation of adverse events. Smoking is permitted, but tobacco intake should be expected to remain consistent throughout the study
4. History of recreational drug use within 14 days of screening or a positive drug screen on day of screening
5. Any medication taken listed in Section 8.3 of the protocol (Interaction with other drugs) including over-the-counter medications and herbal products, within 28 days of screening with the exception of vitamins and/or paracetamol. When a concomitant medication is necessary this will be reviewed by the investigator and if not contraindicated may be continued
6. History of drug sensitivity or drug allergy which in the opinion of the investigator may put the patient at increased risk of drug reactions during the study
7. Patients with female partners who are not using 2 effective forms of contraception or with partners who are pregnant
8. Documented resistance of clinical relevance to any other class of HIV antiretroviral drugs
9. Previous exposure to fusion inhibitors (T20/enfuvirtide)
10. Receiving ART within 6 months of screening

**Date of first enrolment**

01/03/2015

**Date of final enrolment**

01/12/2015

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

### St Mary's Hospital

Imperial College Healthcare NHS Trust

10th Floor QEOM Building Imperial College

St Mary's Campus

South Wharf Road

London

United Kingdom

W2 1NY

# Sponsor information

## Organisation

Imperial College London

## Sponsor details

Joint Research Compliance Office

Charing Cross Hospital

Fulham Palace Road

London

England

United Kingdom

W6 8RF

## Sponsor type

University/education

## ROR

<https://ror.org/041kmwe10>

# Funder(s)

## Funder type

Government

**Funder Name**

Medical Research Council

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

A meeting will be held at the end of the study to provide the results to participants who have taken part in the study. In addition results will be published in peer reviewed scientific journals and presented at conferences at the end of the study.

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	25/08/2017		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No