

A study to test whether a nasal antibody spray can help reduce flu infection in healthy adults, using a controlled research setting where volunteers are exposed to flu under medical supervision

Submission date 09/06/2026	Recruitment status Recruiting	☒ Prospectively registered ☐ Protocol
Registration date 31/07/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 02/09/2026	Condition category Infections and Infestations	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Influenza (flu) illness affects millions of people every year despite available vaccines. Flu vaccine effectiveness averages around 50% because of vaccine strains not matching flu strains in the community. CR9114 is an antibody that is being developed to prevent flu illness regardless of flu strains.

This study is testing CR9114 nasal spray antibody in healthy adults. The study will look at whether the spray is safe, how it behaves in the body, and whether it can help reduce flu infection.

CR9114 nasal spray has been studied in 175 healthy adults without clinical concerns. No allergic reactions were observed. Anti-drug antibodies were observed in 1/175 participants, which was already present at baseline, and without any clinical consequences

Who can participate?

Healthy adults aged 18 to 55 years who fit the specific study criteria will be invited to take part.

What does the study involve?

Participants who are eligible to take part will be randomly assigned to receive either CR9114 or a placebo nasal spray (a spray without active medicine). Neither the participant nor the study team will know which treatment has been given.

Participants will stay as in-patient in a specialized clinical research unit for 12-13 days and will be closely monitored by experienced medical staff throughout the study. Total participation is approximately 5 months.

The study has two parts:

In both Part A and Part B, participants will receive CR9114 or placebo nasal spray for 10 days to see if the spray is safe and tolerated, and how it works in the body. During the study, blood and nasal samples will be taken which could cause discomfort.

In Part B only, participants will take part in a carefully controlled research model where they are given a flu virus under close medical supervision. This allows researchers to understand whether the nasal spray can help reduce flu infection. Controlled inoculation is necessary to test efficacy in a reproducible, closely supervised setting. Symptoms of flu typically include runny nose, congestion, fever, malaise, muscle aches, and sore throat, usually resolving within 3–7 days.

What are the possible benefits and risks of participating?

It is not known if there will be any benefits from joining this study. The researchers are trying to see if CR9114 can improve flu prevention. CR9114 has been studied in 3 studies with good safety profile. The specific flu challenge virus has been safely administered by hVIVO without clinical concerns.

Where is the study run from?

The study is sponsored by Leyden Laboratories B.V. and will take place at hVIVO, a specialist influenza research unit in the United Kingdom.

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

August 2026 to March 2027.

Who is funding the study?

Leyden Laboratories B.V. (Netherlands)

Who is the main contact?

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Contact information

Type(s)

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Additional identifiers

Integrated Research Application System (IRAS)

1013833

Sponsor's protocol code number

F21-CLD-203

Study information

Scientific Title

A phase 2a, single-center, two-part, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of intranasally administered CR9114 monoclonal antibody in healthy adults in a human influenza challenge model

Acronym

F21-CLD-203 (CR9114 Human influenza A challenge model)

Study objectives

This study aims to answer two questions:

Part A: Is the nasal spray antibody CR9114 safe and well tolerated when given for 10 days to healthy adults, and how does it behave in the body?

Part B: Can CR9114 nasal spray reduce flu infection in healthy adults who are deliberately given flu virus in a controlled clinical setting?

CR9114 is a new antibody medicine designed to protect against influenza (flu) A and B. Unlike flu vaccines, it works by directly blocking the virus rather than training the immune system. If effective, it could offer rapid protection against flu, including strains not covered by current vaccines.

Secondary objectives:

Part A: How much of the antibody reaches the bloodstream and nasal lining after dosing, and does the body produce any immune response against it?

Part B:

Does CR9114 reduce the amount of flu virus in the nose after challenge?

Does CR9114 reduce the chance of getting a confirmed flu infection, including infections with symptoms or fever?

Is CR9114 safe and well tolerated when given alongside deliberate flu challenge?

How does CR9114 behave in the body during the challenge period?

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 30/07/2026, West Midlands – Edgbaston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; no telephone number provided; edgbaston.rec@hra.nhs.uk), ref: 26/WM/0124

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Placebo

Assignment

Parallel

Purpose

Prophylaxis

Study type(s)**Health condition(s) or problem(s) studied**

Healthy volunteers. Intended indication for CR9114 monoclonal antibody under development: prevention (prophylaxis) of influenza A and B infections in adults.

Interventions

Following a screening visit, participants will be admitted to the clinical trial site for study drug administration, participants in part B will also receive a single viral challenge with influenza A /H1N1. Participants will be randomized to intranasal CR9114 or intranasal placebo. Participants will be followed up as inpatients during the dosing period to check for adverse events and effect of the drug on influenza infection in part B only. The participants will be discharged the day after last study drug administration and undergo a final ambulatory visit at day 28.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

CR9114

Primary outcome(s)

Part A — Primary endpoint:

Occurrence of treatment-emergent adverse events (TEAEs), including serious adverse events (SAEs), from first IMP administration up to the last follow-up visit (Day 28)

Part B — Primary endpoint:

Area under the viral load-time curve (VL-AUC) of influenza A/H1N1 challenge virus, measured by qRT-PCR on nasal samples collected during the post-challenge quarantine period from Day 1 to Day 8

Key secondary outcome(s)

Part A — Secondary Endpoints:

1. PK: CR9114 mAb concentrations in serum and nasosorption (epithelial lining fluid) samples at protocol-specified timepoints
2. Immunogenicity: Presence of anti-drug antibodies (ADAs) in serum

Part B — Secondary Endpoints:

Efficacy endpoints are assessed during the post-challenge quarantine period from Day 1 to Day 8

Efficacy — Viral load:

1. VL-AUC of influenza A challenge virus, measured by viral culture
2. Peak VL, time to peak VL, time to resolution of VL, measured by qRT-PCR or viral culture

Efficacy — Infection incidence:

3. Laboratory-confirmed influenza infection, measured by qRT-PCR or culture, with and without specified symptoms

Efficacy — Symptoms:

4. Total Symptom Score (TSS) AUC, peak TSS, peak daily symptoms and time to symptoms resolution

Safety:

5. TEAEs (including SAEs) from first IMP administration through Day 28 follow-up
6. SAEs related to challenge agent from Day 0 through Day 28 follow-up
7. Concomitant medication use from Day 0 through Day 28 follow-up

PK and Immunogenicity:

8. CR9114 mAb concentrations in serum and nasosorption samples at protocol-specified timepoints
9. Presence of ADAs in serum

Completion date

25/03/2027

Eligibility

Key inclusion criteria

1. Written informed consent signed and dated by the participant and the PI/investigator obtained before any assessment is performed
2. Aged between 18 and 55 years old on the day prior to signing the consent form
3. Total body weight ≥ 50 kg and BMI ≥ 18 kg/m² and ≤ 35 kg/m²
4. In good health with no history or current evidence of clinically significant medical conditions
5. Females of non-childbearing potential or females of childbearing potential with negative pregnancy test and use of highly effective contraceptive method from 2 weeks before first study visit until 28 days after last IMP dose
6. Serosuitable for the challenge agent (Part B only): serology indicating susceptibility to influenza A/H1N1 challenge virus

Healthy volunteers allowed

Yes

Age group

Adult

Lower age limit

18 Years

Upper age limit

55 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. History of or currently active symptoms of upper or lower respiratory tract infection within 4 weeks prior to first study visit
2. Any clinically significant or active disease that may interfere with study participation per PI or investigator
3. Current smoker, or ex-smoker who ceased within the past 6 months, or cumulative smoking history ≥ 10 pack-years including significant vaping history
4. Females who are breastfeeding, have been pregnant within 6 months prior to the study
5. Lifetime history of anaphylaxis or severe allergic reaction, or significant food or drug intolerance in the last 12 months
6. Significant anatomical nasal abnormality, clinically significant epistaxis within 3 months
7. Within 180 days prior to viral challenge: receipt of influenza vaccine or antiviral medication for influenza or have confirmed influenza illness
8. Receipt of any vaccination within 4 weeks prior to first IMP dose, or intention to receive vaccination before end of follow-up
9. Receipt of any investigational drug within 3 months prior to first IMP dose
10. Immunomodulatory drugs or systemic or intranasal corticosteroids within 6 months prior to first IMP dose, systemic antivirals within 4 weeks, or chronic intranasal medications within 3 months
11. Positive HIV, hepatitis B, or hepatitis C test
12. Positive drug screen on admission

Date of first enrolment

25/08/2026

Date of final enrolment

22/02/2027

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

hVIVO Services Limited

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E14 5NR

Study participating centre

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Sponsor information

Organisation

Leyden Laboratories B.V.

Funder(s)

Funder type

Funder Name

Leyden Laboratories B.V.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available