# A randomized, blinded, placebo-controlled study to assess the safety, tolerability and pharmacokinetics of EGT710 following administration of single and multiple doses to healthy adults.

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| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Viral infectious disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON53410

**Source**
ToetsingOnline

**Brief title**
Safety, Tolerability, and Pharmacokinetics of EGT710 in HV.

### Condition

- Viral infectious disorders

**Synonym**
COVID-19, infectious disease caused by the SARS-CoV-2 virus (coronavirus)

**Research involving**

Human

## Sponsors and support

**Primary sponsor:** Novartis Pharma AG
**Source(s) of monetary or material Support:** Pharmaceutical Industry

## Intervention

**Keyword:** EGT710, Pharmacokinetics, Safety, Tolerability

## Outcome measures

### Primary outcome

• To assess the safety and tolerability of EGT710 following administration of

single and multiple oral doses.

### Secondary outcome

• To evaluate the pharmacokinetics of EGT710 following administration of single

and multiple oral doses.

• To estimate the relative bioavailability of EGT710 following a single dose

administration of Formulation 2 (test formulation) relative to Formulation 1

(reference formulation) under fasting conditions.

• To evaluate the effect of food on the PK of EGT710 following administration

of a single oral dose.

# Study description

### Background summary

EGT710 is a new compound that may potentially be used for the treatment of coronavirus disease 2019 (COVID 19). EGT710 works by inhibiting the coronavirus main protease. This protease is a protein which enables the coronavirus to replicate itself. Inhibition of the coronavirus main protease would reduce the amount of coronavirus and could be proven an effective treatment for COVID 19.

EGT710 is found to have activity against all known human coronaviruses.

**Study objective**

The purpose of the study is to see if the study compound (EGT710) is safe and tolerated when given to healthy adults. The study will also look at how the body absorbs, breaks down, and gets rid of the study treatment.

Approximately 100 healthy volunteers between the ages of 18 and 65 years are being invited to join this study. If you wish to have further details on who can join, please ask the responsible doctor.

Eligibility criteria for this study require that you are a healthy person. The study compound given as part of this study is not being given to treat any symptoms or illness. Your option is to either join or not join this study.

There are certain tests/questions you must complete to find out if you meet the requirements to be in the study. If you do not meet these requirements, you cannot take part in the study.

We also look at the effect of your genetic information on your body*s response to EGT710.This part of the study is not mandatory.

We compare the effects of EGT710 with the effects of a placebo. A placebo is a compound without any active ingredient. Please note that when the term *study compound* is used in this document, we mean EGT710, placebo, or both.

EGT710 has not been administered to humans before. It has been extensively tested in the laboratory and on animals.

**Study design**

In total, the volunteer visits the research center twice:
• once for screening.
• once for a stay in the research centre. For the study it is necessary that the volunteer stays in the research center for a period of time.

This is for Part A: 1 period of 6 days (5 nights).
For Part B: 1 period of 12 days (11 nights)
And for Part C: 1 period of 16 days (15 nights)

We expect the volunteers for Part A and B: two days prior to the (first) administration of the study compound in the study center.
And the volunteers for Part C: on the day prior to the (first) administration of the study compound.

Day 1 is the (first) day on which the volunteer receives the research compound. The Part A volunteers leave the study center on Day 4, the Part B volunteers on Day 10, and the Part C volunteers on Day 15 of the study.

• In addition, we call the volunteer once for a follow-up check.

The study compound is given as follows:

Part A: EGT710 or placebo fasted as oral capsules with 240 milliliters (mL) of (tap) water
The subjects will be divided into six different groups. Whether the volunteer will receive EGT710 or placebo will be determined by chance. Per group, 6 subjects will receive EGT710 and 2 subjects will receive placebo.

Part B: EGT710 or placebo fasted as oral capsules with 240 milliliters (ml) of (tap) water.
The subjects will be divided into four different groups. Whether the volunteer will receive EGT710 or placebo will be determined by chance. Per group, 6 subjects will receive EGT710 and 2 subjects will receive placebo.

Part C: EGT710 or placebo as oral capsules with 240 milliliters (ml) of (tap) water. The volunteer will also receive EGT710 or placebo as oral (test) formulation 2, which is yet to be determined.
The subjects will be divided into six groups with 3 subjects in each. All subjects will receive the study compound once with a breakfast and twice without breakfast. The order in which this will occur will be determined by chance.
The sequence in which the volunteer will receive EGT710 as an oral capsule or as oral formulation 2 will be determined by chance. Each group will receive EGT710 once as oral capsule and twice as oral formulation 2.

**Intervention**

How much and how often the study compound is given:

Part A:
Group 1 will receive 80 mg EGT710 or placebo once on day 1 as oral capsules under fasted conditions.
Group 2 will receive 240 mg of EGT710 or placebo once on day 1 as oral capsules under fasted conditions.
Group 3 will receive 720 mg EGT710 or placebo once on day 1 as oral capsules under fasted conditions.
Group 4 will receive NTB* mg EGT710 or placebo once on day 1 as oral capsules under fasted conditions.
Group 5 will receive 1440 mg of EGT710 or placebo once on day 1 as oral capsules under fasted conditions.

Group 6 will receive NTB* mg EGT710 or placebo once on day 1 as oral capsules under fasted conditions.
* To be determined (NTB)

Part B:
Group 1 will receive 300 mg of EGT710 or placebo once daily on Days 1 to 7 as oral capsules under fasted conditions.
Group 2 will receive 600 mg EGT710 or placebo once daily on Days 1 to 7 as oral capsules under fasted conditions.
Group 3 will receive 1000 mg EGT710 or placebo once daily on Days 1 to 7 as oral capsules under fasted conditions.
Group 4 will receive NTB* mg EGT710 or placebo once daily on Days 1 to 7 as oral capsules under fasted conditions.
* To be determined (NTB)

Part C:
There are 3 treatments in this part of the study, the volunteer will receive all three. The order in which the volunteer receives the treatments is determined by drawing lots. There are 5 days between each dose.

- Treatment 1: EGT710 as an oral capsule after fasting
- Treatment 2: EGT710 as oral formulation 2 after fasting
- Treatment 3: EGT710 as oral formulation 2 after receiving a high fat breakfast.

Dose escalation increments and actual doses may be revised at dose escalation meetings based on safety, tolerability, and pharmacokinetic data from the preceding cohort/dose level.

**Study burden and risks**

Blood draw
Drawing blood may be painful or cause some bruising. The use of the indwelling cannula (a tube in a vein in the arm) can sometimes lead to inflammation, swelling, hardening of the vein, blood clotting, and bleeding in the environment (bruising) of the puncture site. In some individuals, a blood draw can sometimes cause pallor, nausea, sweating, low heart rate, or drop in blood pressure with dizziness or fainting.

In total, we will take about 105 (Part A), 280 (Part B) or 225 (Part C) milliliters (mL) of blood from screening to follow-up. This amount does not cause any problems in adults. To compare: a blood donation involves 500 mL of blood being taken each time at once. If the investigator thinks it is necessary for the safety of a subject, extra samples might be taken for possible additional testing. If this happens, the total amount of blood drawn may be more than the amount indicated above.

Heart tracing
To make a heart tracing, electrodes (small, plastic patches) will be placed on your arms, chest and legs. Prolonged use of these electrodes can cause skin irritation (rash and itching).

Meals/Fasting
The high-fat breakfast is a big breakfast containing e.g., 2 fried eggs, fried potatoes and bacon. The volunteer must consume the whole breakfast. It can be difficult to consume the entire breakfast, particularly for light eaters.

If the volunteer has to fast for a prolonged time during the study, this may lead to symptoms such as dizziness, headache, stomach upset, or fainting.

Coronavirus test
Samples for the coronavirus test will be taken from the back of the nose and throat using swabs. Taking the samples only takes a few seconds, but can cause discomfort and can give an unpleasant feeling. Taking a sample from the back of the throat may cause gagging. When the sample is taken from the back of the nose, the volunteer may experience a stinging sensation and eyes may become watery.

# Contacts

**Public**
Novartis Pharma AG

Lichtstrasse 35
Basel 4056
CH
**Scientific**
Novartis Pharma AG

Lichtstrasse 35
Basel 4056
CH

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

• Able and willing to provide written informed consent.
• Healthy male or female participants 18 to 65 years of age, inclusive, at the time of screening, and in good health as determined by past medical history, physical examination, vital signs, electrocardiogram, and laboratory tests at screening and baseline.
• Participants must weigh at least 50 kg at screening and baseline to participate in the study, and must have a body mass index (BMI) of less than or equal to 35.0 kg/m2. BMI = Body weight (kg) / [Height (m)]2.

Further criteria apply, see protocol.

## Exclusion criteria

•Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant. All potential female participants will be considered physiologically able to become pregnant UNLESS they have had:
(i) 12 months of natural (spontaneous) amenorrhea with an appropriate clinical profile (e.g. age-appropriate amenorrhea, history of vasomotor symptoms) or
(ii) surgical bilateral oophorectomy (with or without hysterectomy) or total hysterectomy at least six weeks prior to screening with confirmatory FSH measurements at screening.
• Sexually active males unwilling to use a condom during intercourse while taking study treatment and for 4 weeks after stopping study treatment. A condom is required for all sexually active male participants to prevent them from fathering a child AND to prevent delivery of study treatment via seminal fluid to their partner. In addition, male participants must not donate sperm for the time period specified above.
• Significant illness which has not completely resolved within one (1) week prior to initial dosing.
•Use of other investigational drugs at the time of enrollment, or within 5 half-lives of enrollment (if known), or within 30 days, whichever is longer; or longer if required by local regulations.

Further criteria apply, see protocol.

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |
| Primary purpose: | Treatment |

## Recruitment

NL

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| Recruitment status: | Completed |
| Start date (anticipated): | 03-10-2022 |
| Enrollment: | 100 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 21-09-2022 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 29-09-2022 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 25-11-2022 |
| Application type: | Amendment |

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| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 29-11-2022 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 28-04-2023 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 09-05-2023 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2022-001905-37-NL |
| CCMO | NL81923.056.22 |

# Study results

Date completed: 30-09-2023

Results posted: 16-05-2024

**First publication**
12-04-2024