

# Investigating the effects of recommended - but unproven - therapies for anaphylaxis in a human histamine challenge model

<b>Submission date</b> 02/08/2024	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/08/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/08/2024	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Anaphylaxis is a life-threatening allergic reaction that happens very quickly. Epinephrine and other interventions are recommended for the treatment of anaphylaxis. However, there is no evidence for effectiveness from randomized controlled trials. The aim of this trial is to compare the treatments recommended in anaphylaxis guidelines in a randomised controlled trial in healthy volunteers challenged with histamine.

### Who can participate?

Healthy volunteers aged 18 years and over

### What does the study involve?

Healthy volunteers will undergo a histamine challenge to lower blood pressure in order to test interventions that may raise blood pressure (injections of adrenaline, infusion of fluid and elevation of legs).

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

As histamine has rapidly reversible actions the risks are limited mainly to blood sampling and side effects such as flushing and headache. There will be no direct benefit for the participants other than information from the performed health tests.

### Where is the study run from?

Medical University of Vienna (Austria)

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

March 2022 to January 2030

### Who is funding the study?

Investigator initiated funding not yet secured

Who is the main contact?  
Prof. Bernd Jilma, MD, bernd.jilma@meduniwien.ac.at

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Prof Bernd Jilma

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

2022-003591-16

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

Histamine infusion in healthy volunteers to study changes in biomarkers and effects of therapeutic interventions – a pilot study

### Acronym

EPI/HIS

### Study objectives

Histamine challenge can be used as a surrogate to examine therapies to treat anaphylaxis

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 21/03/2022, Medical University of Vienna (Borschkegasse, Vienna, 1090, Austria; +43 (0)140400; ethik-kom@meduniwien.ac.at), ref: IRB00002503

**Study design**

Partly randomized controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment, Efficacy

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

Shock

**Interventions**

Recommended interventions for anaphylaxis treatment; this is part of the adaptive trial design and may change. Additional arms may be added in the platform trial approach

1. Elevation of legs (10 min)
2. Volume of crystalloids 10 ml/kg over 10 min
3. Control injection of placebo (same volume as adrenaline)
4. Adrenaline doses as recommended in current anaphylaxis guidelines

**Intervention Type**

Mixed

**Primary outcome(s)**

Mean arterial blood pressure measured with an automated device over 15 minutes during histamine infusion

**Key secondary outcome(s)**

1. Diastolic and systolic blood pressure with an automated device measured over 15 minutes during histamine infusion
2. Pharmacokinetics of adrenaline measured with qualified mass spectrometry assays over 60 minutes

**Completion date**

01/01/2030

**Eligibility****Key inclusion criteria**

Healthy volunteers

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Non-healthy
2. Pregnant
3. Breastfeeding

**Date of first enrolment**

15/08/2024

**Date of final enrolment**

01/01/2030

**Locations****Countries of recruitment**

Austria

**Study participating centre****Medical University of Vienna**

Dept of Clinical Pharmacology

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**Sponsor information****Organisation**

Medical University of Vienna

**ROR**

<https://ror.org/05n3x4p02>

**Funder(s)****Funder type**

Other

**Funder Name**

Investigator initiated funding not yet secured

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

Due to data protection issues, only anonymized data will be shared with qualified researchers. Prof. Bernd Jilma (bernd.jilma@meduniwien.ac.at) should be contacted for access to datasets, anonymized raw data of the primary and secondary endpoints will be shared with qualified investigators once the related manuscripts have been published, and the request has been cleared by the institution's data protection unit.

**IPD sharing plan summary**

Available on request, Other