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

Submission date 02/08/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 05/08/2024	**Overall study status** Ongoing	
Last Edited 05/08/2024	**Condition category** Other	

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 form 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

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Additional identifiers

EudraCT/CTIS number
2022-003591-16

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Partly randomized adaptive trial

Study setting(s)
Hospital

Study type(s)
Treatment, Efficacy

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

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

Secondary outcome measures
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

Overall study start date
21/03/2022

Completion date

01/01/2030

Eligibility

Key inclusion criteria
Healthy volunteers

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
The sample size will depend on the observed effect sizes and the variability thereof and can only be determined after the pilot trial has been completed

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
Währingergerürtel 18-20
Wien
Austria
1090

Sponsor information

Organisation
Medical University of Vienna

Sponsor details
Spitalgasse 23
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Sponsor type
University/education

Website
http://www.meduniwien.ac.at/homepage/1/homepage/

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
Other

Funder Name
Investigator initiated funding not yet secured

Results and Publications

Publication and dissemination plan
Results will be presented at international conferences and in peer-reviewed journals

Intention to publish date
01/01/2027

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