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Diagnosing allergies with Skin Prick Automated Test (S.P.A.T.)

Submission date	Recruitment status	[_] Prospectively registered
06/07/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/07/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/08/2024	Other	

Plain English summary of protocol

Background and study aims
Allergies affect 30-40% of the general population. The skin prick test is the golden standard to diagnose allergies against for example pollen, dust or food allergies. However, variable results are obtained dependent on who executes the test and on which device is used. In order to reduce this variability, an automated skin prick test device was developed and is being validated in this study.

Who can participate?
Healthy volunteers aged between 18 and 65 years old

What does the study involve?
Participants will be recruited via regular communication channels at UZ Leuven in May 2022. These individuals are asked to undergo two series of skin prick tests, one manual (arm 1) and one automated (arm 2). Both skin prick tests are performed with 9 pricks of histamine, from which a red, itchy inflamed wheal is expected on the skin, and 1 prick of glycerol control solution from which there should be no reaction.

What are the possible benefits and risks of participating?
There is no immediate personal benefit for the participants. The Risks of participating are skin itch and redness or erythema (seldom). Uticaria also known as hives, weals, welts or nettle rash, asthma attack or anaphylaxis are rare.

Where is the study run from?
University Hospital Leuven (Belgium)

When is the study starting and how long is it expected to run for?
March 2022 to May 2022

Who is funding the study?
Hippo dx (Belgium)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Validation and reproducibility of Type I hypersensitivity reaction in the diagnostic process of the skin prick test: Manual versus automated testing

Study objectives
Allergies are a major problem in global patient care, multiple methods of diagnosis have been created of which the skin prick test is the golden standard. This test, first described in the literature in 1959, has not changed over the last 60 years and is still performed manually and needs to be executed by experienced personnel.

Often human error means that this test can be inaccurate and because of workload, some health care providers move to other less sensitive diagnosis methods.

To improve accuracy and take out human error, Hippo Dx developed Skin Prick Automated Test (S.P.A.T.) an automated skin prick test. This study will provide a comparison between manual and automated skin prick tests.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 09/05/2022, Federal Agency for Medicines and Health Products (FAHMP) of Belgium (Avenue Galilée - Galileelaan 5/03,1210, Brussels; +32 (0)2 528 44 86; annemie.zenner@fagg-afmps.be), ref: CIV-22-03-039130

Study design
Prospective single-centre study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Allergy diagnostics

Interventions
Participants will be recruited via regular communication channels at UZ Leuven in May 2022. The individuals will be divided into decade age groups (i.e. sample size). Only adult subjects (18 to 65 years old) are included, this age range consists of the same population where a manual skin prick test will be performed according to international standards in skin prick testing. The participants will undergo a manual (arm 1) and an automated (arm 2) skin prick test; the automated test uses a clinical device by Hippo Dx: S.P.A.T. (skin prick automated test). Both skin prick tests are performed with 9 pricks of histamine, from which a red, itchy inflamed wheal is expected on the skin, and 1 prick of glycerol control solution from which no reaction is expected.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome(s)
Coefficient of variation wheal size (mm) measured using manual skin prick test (SPT) and SPAT at 15 minutes after skin prick

Key secondary outcome(s))
Number of true positive and true negative wheals using manual skin prick test (SPT) and SPAT at 15 minutes after skin prick

Completion date
31/05/2022

Eligibility

Key inclusion criteria

Aged between 18 and 65 years old

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
118

Key exclusion criteria
1. Skin pathologies like chronic or exuberant urticaria, dermographism, and chronic dermatitis that need daily treatment
2. Use of antihistaminic medication < 7 days before the start of the study
3. Use of tricyclic antidepressants (antihistamine activity) < 7 days before the start of the study
4. Use of topical corticoids on the forearm < 7 days before the start of the study
5. Use of omalizumab < 6 months before the start of the study
6. Pregnancy

Date of first enrolment
20/05/2022

Date of final enrolment
31/05/2022

Locations

Countries of recruitment
Belgium

Study participating centre
University Hospitals Leuven
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Sponsor information

Organisation
Hippo DX

Funder(s)

Funder type
Industry

Funder Name
Hippo Dx

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/12/2022	02/06/2023	Yes	No
Results article		01/11/2023	05/08/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes