Brain activity in Urticaria Factitia using neurophysiological imaging

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The aim of this study is to investigate alterations in brain activity in UF patients by detecting and characterizing MEG changes, using network theory.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Angioedema and urticaria
Study type	Observational invasive

Summary

ID

NL-OMON46276

Source
ToetsingOnline

Brief title
Brain in Urticaria Factitia

Condition

- Angioedema and urticaria

Synonym
dermographism, skin writing

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: non-restricted grant van Novo Nordisk

Intervention

Keyword: Magnetoencephalography, Urticaria Factitia

Outcome measures

Primary outcome

- Difference in local and global connectivity between UF patients and healthy controls during the baseline measurement

- Difference in local and global connectivity between UF patients and healthy controls after a histamine prick test

- Difference in local and global connectivity between UF patients and healthy controls after dermography

Secondary outcome

- Differences in the itch score (VAS) before and after a histamine prick test and dermography, DASS and serum levels of CRH, ACTH, prolactine, cortisol, NGF, BDNF, SP between UF patients and the control group.

- Correlation between *global connectivity* after a histamine prick test and the itch score (VAS), area of a histamine prick test wheal and flare, UCT, CU-Q2oL, DASS and serum levels of CRH, ACTH, prolactine, cortisol, NGF, BDNF, SP.

- Correlation between *global connectivity* after dermography and the itch score (VAS), width of the dermography wheal, UCT, CU-Q2oL, DASS and serum levels of CRH, ACTH, prolactine, cortisol, NGF, BDNF, SP

In case of detectable regional differences in connectivity measures after a histamine prick test or dermography between UF patients and the control group:

- Correlation between *local connectivity* after a histamine prick test and the

itch score (VAS), area of a histamine prick test wheal and flare, UCT, CU-Q2oL,

DASS and serum levels of CRH, ACTH, prolactine, cortisol, NGF, BDNF, SP.

- Correlation between *local connectivity* after dermography and the itch score

(VAS), width of the dermography wheal, UCT, CU-Q2oL, DASS and serum levels of

CRH, ACTH, prolactine, cortisol, NGF, BDNF, SP.

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Study description

Background summary

Chronic urticaria, which is appearing in different forms, is a common disease. In this research urticaria factitia (UF), which is precipitated by stroking or scratching, will be examined. In all forms of urticaria the etiology is still unknown. In chronic urticaria, as in other skin diseases, psychological stress is an important contributing factor. Besides, recent research has been done in the relationship between brain activity and skin disease, where by means of functional MRI (fMRI) was demonstrated that some brain regions are more or less activated in atopic dermatitis patients compared to healthy controls. With this knowledge a role for the brain in urticaria is hypothesized. Understanding the origin of urticaria factitia with the use of MEG (magnetoencephalography, a recording of magnetic fields related to brain activity) and modern network theory can help to unravel the etiology of urticaria factitia

Study objective

The aim of this study is to investigate alterations in brain activity in UF patients by detecting and characterizing MEG changes, using network theory.

Study design

This investigation is a hypothesis inducing study on which the 'proof of concept' approach is applicable since there is no previous study on this topic. MEG and modern network theory is used to study functional network alterations in UF patients compared to healthy controls.

Intervention

Three conditions are studied during the MEG-measurement: baseline situation,

local whealing after a histamine prick test, and local whealing after stroking (dermographism).

Study burden and risks

MEG measurements are non-invasive, taking approximately 1,5 hours, including preperation and testing between the measures. The procedure is not painful in any way, is not considered to be difficult or stressful, and has negligible risks. The same holds true for histamine prick testing and dermography. The participants are asked to visit VU Medical Centre for the investigations. There is no individual benefit from the MEG. The MEG recordings have a higher spatial resolution compared to the conventional electroencephalography (EEG). Since MEG measures brain activity directly, MEG is favoured compared to fMRI. Total visit time: 2,5 hours.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

UF diagnosed by a dermatologist, in active phase, i.e., wheals arise when antihistaminic drugs are stopped
18 years or older
informed consent given

Exclusion criteria

Age < 18 years
Participants that cannot read, speak or understand Dutch
Mentally incompetent individuals who are not capable to provide informed consent, as determined by their treating physician
Conditions that will cause excessive MEG artefacts (cardiac pacemaker/cardiac or neural defibrillators, metal fragments in the eyes, metal plates, piercings, pins or bolts in head, any magnetic implantation/implantations made from iron (ferrous products)
Systemic medication: corticosteroids, ciclosporine, montelukast, hydroxychloroquine, dapson, omalizumab, methotrexate
The antihistaminic drug should be stopped 4 days in advance
For healthy controls: participants with a history of any form of urticaria and participants who use antihistaminic drugs

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	11-04-2017
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	02-12-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL58260.029.16