Anatomical and Functional Plasticity in the Olfactory System

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and hereditary disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON45323

Source
ToetsingOnline

Brief title
From the nose to the brain

Condition

- Congenital and hereditary disorders NEC

Synonym
born without the sense of smell, congenital anosmia

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: brain morphology, congenital anosmia, olfaction, sensory integration

Outcome measures

Primary outcome

Main parameters within this study are:

- Morphological (anatomical) differences in brain areas between healthy and anosmic individuals.

- Differences in functional connectivity during resting-state between healthy and anosmic individuals.

- Differences in functional connectivity during uni- versus multi-sensory stimulation within healthy and anosmic individuals.

- Differences in functional connectivity during uni- and multi-sensory stimulation between healthy and anosmic individuals.

Secondary outcome

A secondary study parameter are differences between groups in behavioral outcomes of the multisensory integration task. This will be calculated by means of Hierarchical Drift Diffusion Model (HDDM), to combine speed versus accuracy in responses.

Study description

Background summary

In contrast to the three sensory modalities of vision, audition, and touch, few studies have explored what impact sensory loss in the chemical senses (olfaction and gustation) might have on our cortical organization and behavioral performance. The few studies that have explored cerebral changes

mediated by a loss of olfactory functions demonstrate remarkable little changes in either morphology or functional remapping.
To date, studies exploring anosmia-related morphological changes have utilized classical voxel-based GLM analyses where large localized changes is needed to reach statistically established levels. This project is based on the assumption that changes within such wide-spread network that encompass only heterogeneous processing areas should demonstrate subtle but wide-spread alteration rather than uniquely impacting one specific area. Thus, by using novel multivoxel- and network-based analyzing techniques, we can define and characterize anosmia-related neural plasticity in the human brain from a network perspective rather from than of a single-voxel.
Finally, previous studies exploring blind and deaf individuals have demonstrated enhancement of sensory functions in remaining sensory modalities but none have assessed whether sensory loss alters individuals ability to integrate and utilize information gain from multiple sensory sources, so-called sensory integration gain.

Study objective

The overall goal of this project is to define and characterize congenital anosmia-related neural plasticity in the human brain and its behavioral consequences. We hypothesize that individuals suffering from congenital anosmia demonstrate wide-spread morphological changes and that these changes render them be better at multisensory integration tasks.

We will investigate the following two major issues in the proposed experiments:
1) Are there differences in the basic morphology and functionality of the human brain between humans who were born with and humans who were born without the sense of smell?
2) Are there differences in neural processing of other senses (vision and hearing) between humans who were born with and humans who were born without the sense of smell?

Study design

This is an observational case-control study. Duration of the protocol will be one session of 2 hours. On the study day participants will perform a behavioural task (Sniffin' Sticks smell test) as well as engage in an fMRI session that consists of four subparts:
* Whole brain anatomical image
* Functional resting-state scan
* Multisensory integration task consisting of identifying objects within degraded stimuli
* Object identification task of clear visual and auditory objects.

Study burden and risks

The study is non-therapeutic to the participants. No immediate benefits for the participants are expected from participation in this study. The risk associated with participation is negligible. The participant*s burden is as follows, regarding time: the experimental session will take approximately 2hrs: one hour of behavioral (olfactory) testing, and one hour inside the scanner. MRI is an eminently safe technique; there are no risks that have been associated with the acquisition of MRI data per se.
Chance findings of pathology: The MRI-scans in this study are not made with the intention to diagnose pathologies, however, chance findings of pathology may occur. Participants will be informed of this possibility and need to be willing to receive information about incidental findings of pathology, as this is one of the inclusion criteria. In case of a possible chance finding, a radiologist will inspect the scans. If any pathology is found or suspected by the radiologist, the subject will be referred to his/her general physician or a medical specialist. The participant and her/his general physician will be informed of the finding.

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

For patients, in order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Have congenital anosmia
- Labelled as anosmic according to our standardized clinical olfactory test
- Age between 18-65 years
- Have a normal eyesight or an eye deviation that can be corrected with glasses or contact lenses.
- Willing to comply with the study procedures
- Willing to be informed about incidental findings of pathology
- Having given written informed consent;For age- and sex- matched healthy controls, in order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Self-reported healthy
- No know smell disorder
- Labelled as having a normal sense of smell according to our standardized clinical test
- Age between 18-65 years
- Have a normal eyesight or an eye deviation that can be corrected with glasses or contact lenses.
- Willing to comply with the study procedures
- Willing to be informed about incidental findings of pathology
- Having given written informed consent
- Matched on sex to patient
- Matched on age (within 3 years) to patient

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Being deaf (or having any other hearing problems) or blind
- Being an employee of the division of Human Nutrition, Wageningen University
- Performing an internship or thesis at the chair group Sensory Science and Eating Behaviour of the division of Human Nutrition, Wageningen University
- Having a contra-indication to MRI scanning (including, but not limited to):
* Pacemakers and defibrillators
* Intraorbital or intraocular metallic fragments
* Ferromagnetic implants
* Presence of non-removable piercings

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2017
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	15-05-2017
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL60948.081.17