Detecting Multiple Sclerosis via breath analysis using an eNose

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26204

Source
NTR

Brief title
TBA

Health condition

Multiple Sclerosis

Sponsors and support

Primary sponsor: Drs. M.W.P.M. Lenders
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Investigate the accuracy of the AeonoseTM in distinguishing breath prints of patients with various types and stages of MS and sujects without MS, whether it can assist in diagnosing MS, and whether it can monitor its progression.

Secondary outcome

1.Improve the model created in the pilot study by expanding the groups.
2.Determine whether eNose patterns differ for various types and stages of MS.
3.Determine whether eNose patterns differ between MS patients with a positive response to medication and MS patients with no response to medication, to predict and monitor the patients response to treatment.
4.Determine whether our eNose models are able to distinguish between subjects who will be diagnosed with MS and those who will not get the diagnosis MS.

Study description

Background summary

There is not yet a quick test nor a non-invasive method to identify patients with Multiple Sclerosis (MS) or distinguish between various types of MS. An electronic nose is a diagnostic device to detect patterns in the compounds that are exhaled by patients. The disease-specific pathways give rise to specific patterns that aid in detecting diseases. Exhaled breath data and clinical parameters will be used to develop a predictive model, based on supervised machine learning techniques. We will investigate whether an eNose can detect MS and monitor the disease progression.

Study objective

We expect that MS could be detected by an electronic nose by analysing exhaled volatile compound patterns.

Study design

One measurement

Intervention

Participants will breathe trough the AeonoseTM for 5 minutes.

Contacts

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Scientific

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Eligibility criteria

Inclusion criteria

Inclusion criteria for patients with MS:
- Diagnosis MS confirmed by a neurologist
- Age >18 years

Inclusion criteria control subjects
- Not suspicious of having MS
- Age >18 years

Exclusion criteria

- Physically or cognitively being unable to use the Aeonose
- Diagnosed with another neurodegenerative or neuroinflammatory disease (besides MS)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2020

Enrollment:	400
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	23-08-2021
Application type:	First submission

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
NTR-new	NL9689
Other	METC Isala : METC201013

Study results

Summary results
Ettema A.R, et al. Detecting Multiple Sclerosis via breath analysis using an eNose, a pilot study. J. Breath Res. 2021, 15, 027101