Detecting Multiple Sclerosis via breath analysis using an eNose, a pilot study

No registrations found.

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

Summary

ID

NL-OMON28252

Source
Nationaal Trial Register

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

Investigating whether the AeonoseTM is able to distinguish breath of patients with confirmed diagnosis of MS and control subjects without any suspicion of MS.

Secondary outcome

Determining whether AeonoseTM patterns differ between patients with MS without medication and control subjects.
Determining whether AeonoseTM patterns differ for various types of MS.

Study description

Background summary

The primary aim of this study is to investigate whether an eNose can detect VOC patterns that
distinguish between patients with confirmed diagnosis of MS and matched subjects withou any suspicion of MS.
Study design: prospective, non-invasive case control study.
Study population: 100 patients diagnosed with MS, 100 control subjects.
Intervention: breathing through an eNose for 5 minutes.
There are no risks involved for the participants.

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 through the AeonoseTM for 5 minutes.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria for patients with MS:
- Diagnosis MS had been confirmed by a neurologist.
- Age ≥ 18 years.

Inclusion criteria control subjects:
- Not suspicious of having MS.
- Age ≥ 18 years.

Exclusion criteria

Subjects who are physically or cognitively unable to use an eNose.

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:	Recruitment stopped
Start date (anticipated):	04-03-2019
Enrollment:	100
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-11-2019
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	NL8146
Other	METC Twente : METC K18-42

Study results