E Nose.

No registrations found.

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

Summary

ID

NL-OMON28353

Source
Nationaal Trial Register

Brief title
E Nose

Health condition

RA, reuma, rheumatoid arthritis

Sponsors and support

Primary sponsor: Academisch Medisch Centrum div Immunology and Rheumatology
Source(s) of monetary or material Support: Academisch Medisch Centrum div Immunology and Rheumatology

Intervention

Outcome measures

Primary outcome

The primary outcome parameter is the smell-print provided by the electronic nose, together with the results of the on-board and offline statistical analysis.

Secondary outcome

N/A

Study description

Background summary

We postulate that exhaled breath sampling by an electronic nose can distinguish:

Patients with rheumatoid arthritis with active disease defined by a disease activity score of 28 joints (DAS28) ≥ 3.2, from non-smoking asymptomatic controls.

Country of recruitment: the Netherlands.

Study objective

We postulate that exhaled breath sampling by an electronic nose can distinguish patients with rheumatoid arthritis with active disease defined by a disease activity score of 28 joints (DAS28) ≥ 3.2, from non-smoking asymptomatic controls.

Study design

One moment, test will be performed in duplo.

Intervention

Methods: Electronic nose: the 'Willem Frederik' (Smith Detections, Pasadena, Ca, USA). When exposed to a gas mixture, the sensors will swell and thus change the electrical conductance, resulting in a unique smell-print. These measurements are stored in an on-board database and can be analyzed by the pattern recognition software as well as by offline statistics software.

Breathing maneuver: Patients will breathe normally through a mouthpiece, connected to a three-way non-re-breathing valve and an inspiratory VOC-filter (A2, North Safety, NL) for 5 minutes. After a single deep inspiration the patient exhales a vital capacity volume into a Tedlar bag connected to the expiratory port. Tests will be performed in duplo.

Contacts

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Eligibility criteria

Inclusion criteria

Rheumatoid arthritis patients:

A minimum of 15 patients 18-75 years with:

1. RA according to the ACR criteria;

2. Rheumatoid factor IgM and/or anti-CCP positive;

3. DAS28 ≥ 3.2;

4. Stable methotrexate use.

Controls:

A minimum of 15 asymptomatic age- and gender matched controls:

1. Non-smoking (< 5 pack-years, > 12 months);

2. A negative test for Rheumatoid factor IgM and anti-CCP.

Exclusion criteria

1. Severe cardiovascular disease, history or present;

2. Myocardial infarction;

3. Coronary bypass surgery;

4. CVA;

5. Pulmonary embolism and deep venous thrombosis;

6. Heart failure;

7. A history of diabetes mellitus;

8. Systemic inflammatory disease other than RA;

9. A history of/or active pulmonary disease, including extra articular manifestation of RA, asthma, COPD, TBC, infection;

10. Cancer diagnosed and treated within 5 years, or known incomplete remission if earlier;

11. Presence or recent history (4 weeks) of paradontitis;

12. History of upper or lower respiratory infection in the past 4 weeks;

13. The use of inhalation medication;

14. Antihistamines, theofylline, and antibiotic use in the past 2 days;

15. The use of corticosteroids, either orally or systemic;

16. The use of intramuscular corticosteroids less than 4 weeks before inclusion;

17. The use of DMARD’s other then methotrexate;

18. Change in methotrexate dosage 28 days or less before inclusion;

19. The use of biologicals, such as anti-TNF agents, B cell depleting agents, IL-6 receptor antagonists, CTLA4Ig;

20. Eating (including chewing gum), drinking, smoking, brushing teeth < 3 hours before measurements;

21. Lack of comprehension of the study and measurements;

22. Pregnancy;

23. A history of hyper- or hypothyroid function or use of Levothyroxine;

24. A history of renal insufficiency.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2010
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-08-2010
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	NL2343
NTR-old	NTR2449
Other	MEC AMC : 10/126
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A