Can breath analysis predict hernia recurrence?

No registrations found.

Ethical review   Not applicable
Status   Pending
Health condition type   -
Study type   Observational non invasive

Summary

ID

NL-OMON25769

Source
Nationaal Trial Register

Health condition

ventral hernia recurrence.

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Breathprint prediction model

Secondary outcome

None

Study description

Background summary

Rationale

Hernia recurrence is observed in 0-52% of the ventral hernia patients, depending on the complexity of the hernia, method of repair and experience of the surgeon. Previous studies have shown that patients who develop hernia recurrences are likely to have a different ratio of collagen I and III, predispositioning then for hernia recurrence. If these patients could be identified in a reliable, low cost, non-invase manner this could effect pre-operative planning, technique for hernia repair and follow-up length.

Exhealed breath contains many volatile organic compounds (VOC) that can be measured using non-specific sensors. These sensors can build a patern or statistical model of the exhaled breath in the effected patients. Building the model will take 25 cases and an equal number of controls.

Objective:

- wheter the eNose can recognise a patern in recurrent hernia patients and descriminate then from healthy controls.

study design:

Observational study using 25 recurrent hernia patients and 25 healthy controls

Study objective

Can the eNose Aerekaprobe be used to create a prediction model based on 25 patients with ventral hernia recurrence?

Study design

None, patients with a hernia recurrence now or in the past can both be included. Patients need to be 'tested' only once.

Intervention

None

Contacts

Public
Elkerliek Hospital

E. H. H. Mommers
Wesselmanlaan 25

[default] 5700 AB
The Netherlands
tel: 0492 595 555
Scientific
Elkerliek Hospital

E. H. H. Mommers
Wesselmanlaan 25

[default] 5700 AB
The Netherlands
tel: 0492 595 555

Eligibility criteria

Inclusion criteria

Any patient with a ventral hernia recurrence.

- age between 18-80 years old

- written informed concent

Exclusion criteria

- groin hernia

- parastomal hernia

- rectus diastasis without true hernia

- Ehlers Dahlos (all types)

- Other (rare) collagen disorders (i.e. Alport, hypochondrogenesis, bethlem myopathy, fuch's dystrophy, etc.)

- Diabetes Mellitus

- Alcohol consumption in past 48 hours

- Pulmonary dissease

- (former) malignancy

- non-smoker or spot smoking >3 months ago

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):	01-08-2016
Enrollment:	25
Type:	Anticipated

Ethics review

Not applicable
Application type:	Not applicable

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	NL5791
NTR-old	NTR5954
Other	: METC 16-4-142

Study results

Summary results
None