OUTER SPACE: a randomised study on inhaler treatment adherence using a smart spacer in adults with asthma

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24135

Source
NTR

Brief title
OUTER SPACE-2

Health condition

asthma

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: Trudell Medical

Intervention

Outcome measures

Primary outcome

To assess the overall feasibility of undertaking a definitive randomized controlled trial on the effects of tailored inhaler education by the GP/nurse supported by a smart spacer, in primary care treated adults with asthma

Secondary outcome

1) determine patient recruitment speed, participation rate (proportion of eligible patients), drop-out rate and inform sample size calculation for a definitive trial.
2) assess patient and healthcare provider satisfaction with the workflow (System Usability Scale [SUS]).
3) explore the distribution of medication adherence patterns (persistence and inhaler technique) and clinical outcomes (lung function, FeNO, Asthma Control Questionnaire [ACQ], Test for Adherence to Inhalers [TAI], and Work Productivity and Activity Impairment questionnaire [WPAI], SABA use, oral steroid bursts)

Study description

Background summary

Aim: To assess the overall feasibility of undertaking a definitive randomized controlled trial of the Smart Spacer device in primary care treated adults with asthma. In particular, we aim to: 1) inform patient recruitment speed, participation rate and sample size calculation for a definitive trial 2) assess patient and healthcare provider satisfaction with the smart spacer and 3) explore the distribution of medication adherence patterns (persistence and inhaler technique) and clinical outcomes.
Smart Spacer: The smart spacer used in this study is the Aerochamber Plus® with Flow Vu®. The smart spacer uses the same components as the existing CE-marked spacer. The smart spacer monitors both persistence and inhalationtechnique.
Methods: Single center, randomized controlled feasibility trial of 2 months. Patients will be recruited from 4 GP practices in the Netherlands. Patients (n=40) will use the smarts spacer for 1 month (t=-1). Then they will be randomized in two groups (t=0). The control group will get usual care, the intervention group will get tailored feedback and education on basis of data from the smart spacer. After 1 month (t=1) the study is ended and patients will get again their usual care.
Outcomes: At t=-1. t=0 and t=1 ACQ, WPAI an TAI questionnaires and FeNO test will be assessed. At t=0 and t=1 a lung function will be tested. At t=1 usability will be analyzed by the SUS questionnaire and structured interviews with 5 patients and all caregivers.

Study objective

The investigational treatment, tailored inhaler use education, supported by data generated by a smart spacer, leads to better adherence.

Study design

at t=-1, t=0 en t=1 (months) earlier mentioned questionnaires will be taken, spirometry and FeNO test will be performed.

Intervention

the intervention group will receive personalized, tailored education by a GP/nurse supported by data of a smart spacer.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
(1) adults >= 18 years;
(2) physician diagnosed asthma treated in primary care;
(3) using any inhaled corticosteroid (ICS) (+/-long-acting beta agonist [LABA] +/- short-acting beta agonist [SABA]) administered by a pressurized Metered Dose Inhaler (pMDI) and a spacer;
(4) willing to sign informed consent.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
(1) < 18 years;
(2) exacerbation in the last 3 months (defined as use of antibiotics and/or prednisone short-course and/or admission to a ED or hospital).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2021
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
data available by reasonable requenst from autors

Ethics review

Positive opinion

Date:	30-06-2021
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	NL9637
Other	METC MCL : 2021 00390

Study results