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

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

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON24135

**Bron**
NTR

**Verkorte titel**
OUTER SPACE-2

**Aandoening**

asthma

### Ondersteuning

**Primaire sponsor:** UMCG
**Overige ondersteuning:** Trudell Medical

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

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

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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

### Onderzoeksopzet

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

### Onderzoeksproduct en/of interventie

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

# Contactpersonen

## Publiek

UMCG
Boudewijn Dierick

0515231770

## Wetenschappelijk

UMCG
Boudewijn Dierick

0515231770

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-10-2021 |
| Aantal proefpersonen: | 40 |
| Type: | Verwachte startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Ja

**Toelichting**
data available by reasonable requenst from autors

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 30-06-2021 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL9637 |
| Ander register | METC MCL : 2021 00390 |

# Resultaten