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Tapering off Inhaled Corticosteroids in Asthma patients after Reduction of Allergens

Submission date	Recruitment status	[_] Prospectively registered
19/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/12/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/08/2009	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR370

Study information

Scientific Title

Acronym
TICARA

Study objectives
Allergen avoidance allows tapering off inhaled corticosteroids (ICS) in house dust mite allergic asthma patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Multicentre randomised double blind placebo controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Asthma, Allergy

Interventions
All patients have been trained to use a self-management plan to adjust the dose of inhaled corticosteroids to symptoms and peak expiratory flow value.
After a run-in period of 3 months the intervention period with placebo controlled allergen avoidance started.
The participants in the intervention group received house dust mite impermeable covers for mattress, pillow and bedding.
The control group received placebo, house dust mite permeable, covers.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Use of inhaled corticosteroids

Secondary outcome measures
1. Asthma control
2. Symptoms (dyspnoea, wheezing, coughing)
3. Peak flow parameters (morning peak flow, peak flow variability)

Overall study start date
01/01/1999

Completion date
01/12/2004

Eligibility

Key inclusion criteria
1. Age 16-60 years
2. Treatment for asthma by the GP
3. Use of inhaled corticosteroids
4. Allergy for house dust mite allergens

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Serious diseases other than asthma with a low survival rate
2. Other diseases, which influence bronchial symptoms and/or lung function
3. Exacerbation within one month before the start of the study
4. The use of oral steroids or inhaled cromoglycates
5. Use of house dust mite impermeable mattress/bedding covers
6. Allergy to cats or dogs while keeping these pets

Date of first enrolment
01/01/1999

Date of final enrolment
01/12/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
University Maastricht
Maastricht
Netherlands
6200 MD

Sponsor information

Organisation
Care and Public Health Research Institute (CAPHRI), University Maastricht (Netherlands)

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Sponsor type
Research organisation

ROR
https://ror.org/02jz4aj89

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Funder Name
Netherlands Asthma Foundation (Netherlands)

Funder Name
Boehringer Ingelheim BV (Netherlands)

Funder Name
AstraZeneca BV (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2006		Yes	No