ISRCTN95392638 https://doi.org/10.1186/ISRCTN95392638

Comparison study of treatment given to children with asthma by a nurse practitioner, a general practitioner or a pediatrician. (Vergelijkende studie met betrekking tot de controle van kinderen met astma door de nurse practitioner, de huisarts of de kinderarts)

Submission date	Recruitment status	[ ] Prospectively registered
11/08/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/08/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/08/2011	Respiratory	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Maarten Kuethe

Contact details
Department of Pediatrics
Amphia hospital
PO Box 90157
Breda
Netherlands
4800 RL

Additional identifiers

Study information

Scientific Title

Comparison study to follow-up of treatment given to children with stable asthma by a nurse practitioner, a general practitioner or a pediatrician: a randomized controlled trial

Acronym
TRAM

Study objectives
TRAM (TRans mural Asthma Management). Treatment of children with stable asthma by a nurse practitioner is not inferior to treatment by a general practitioner or a pediatrician.

Ethics approval required
Old ethics approval format

Ethics approval(s)
TWOR Medical Centre "Rijnmond" South, Rotterdam approved on 11 January 2008, ref: nl. 17972.101.07

Primary study design
Observational

Study design
Randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pediatric asthma

Interventions
Children were randomly assigned to one of the three follow up arm and at baseline, one year & two year a variety of outcome measures were collected.

1. Management by general practitioner
2. Management by paediatrician
3. Management by asthma nurse

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Inhaled corticosteroid (beta-2-agonist), PD20 methacholine

Primary outcome(s)
1. Airway hyper responsiveness
2. PD20 methacholine
Measured at baseline, one year & two year

Key secondary outcome(s)
1. Forced expiratory volume in one second (FEV1) before and after bronchus dilatation with beta-2-agonist
2. Exhaled nitric oxide (NO)
3. Asthma Control Questionaire
4. Health economics
5. Prescribed medication
6. Quality of Care assessment by completing the QUOTE-CNSLD instrument by parents
7. Completion of Likert scale by the children

Completion date
28/01/2009

Eligibility

Key inclusion criteria
1. Children 6-16 years
2. Moderate asthma as defined by the guideline of the dutch pediatric pulmonologists or diagnosed as asthma by their general practioner (GP) and on prophylactic treatment with inhaled corticosteroid (ICS)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Years

Upper age limit
16 Years

Sex
All

Key exclusion criteria
Serious, poorly controlled asthma requiring step intravenous (IV) treatment according to the action plan in the guideline

Date of first enrolment
04/03/2005

Date of final enrolment
28/01/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Department of Pediatrics
Breda
Netherlands
4800 RL

Sponsor information

Organisation
Amphia Hospital (Netherlands)

ROR
https://ror.org/01g21pa45

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Amphia Hospital (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration