

Development and validation of a caregiver quality of life questionnaire for wheezy preschool children

Submission date 24/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 30/09/2016	Condition category Respiratory	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Ms Catherine Olden

Contact details

Respiratory Care
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

-

catherine.olden@bsuh.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Development and validation of a caregiver quality of life questionnaire for wheezy preschool children

Acronym

QOL

Study objectives

To establish a valid and reliable measure of health-related quality of life for caregivers of wheezy preschool children.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Kent Research Ethics Committee, July 2006, ref: 06/Q1905/8

Study design

Single centre non-randomised interventional treatment trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Respiratory; Subtopic: Respiratory (all Subtopics); Disease: Respiratory

Interventions

Item reduction stage:

Asking carers of wheezy preschool children to complete a quality of life (QOL) questionnaire plus two data sheets. It takes about half an hour to complete the questionnaire.

Validation stage:

The final questionnaire will be given to parents to complete on three occasions (over

approximately 8 weeks):

1. At first clinic visit
2. 1 - 2 weeks later before any change in treatment has been made
3. 6 weeks after a change in asthma treatment intended to bring the asthma symptoms under control

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

To have a validated quality of life questionnaire for caregivers of wheezy preschool children

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/01/2010

Completion date

31/12/2010

Eligibility

Key inclusion criteria

1. Boys and girls
2. History of 2 or more wheezing episodes
3. Age 1 year to 5 years 11 months

Participant type(s)

Patient

Age group

Child

Lower age limit

1 Years

Upper age limit

5 Years

Sex

Both

Target number of participants

Planned sample size: 210

Key exclusion criteria

Other major medical problem

Date of first enrolment

01/01/2010

Date of final enrolment

31/12/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Royal Sussex County Hospital

Brighton

United Kingdom

BN2 5BE

Sponsor information

Organisation

Brighton and Sussex University Hospitals NHS Trust (UK)

Sponsor details

Royal Sussex County Hospital

Eastern Road

Brighton

England

United Kingdom

BN2 5BE

Sponsor type

Hospital/treatment centre

Website

<http://www.bsuh.nhs.uk/>

Funder(s)

Funder type

Charity

Funder Name

Asthma UK (UK)

Alternative Name(s)

Asthma UK, Asthma + Lung UK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

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