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The effect of vitamin D supplementation at diagnosis of pneumonia upon response to treatment

Submission date 27/02/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/03/2007	**Overall study status** Completed	
Last Edited 30/10/2008	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Study objectives
There is no difference in the incidence of pneumonias or their severity for children diagnosed with pneumonia supplemented with 100,000 IU vitamin D at the start of the cold season and 3 months later compared to placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of the Ministry of Public Health of Afghanistan. Approved on 19 November 2006. Ref: 237783

Primary study design
Interventional

Study design
Double blind randomised controlled trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Pneumonia

Interventions
Vitamin D3 100,000 IU supplementation vs placebo

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
vitamin D

Primary outcome(s)
Duration of pneumonia as measured from the date of clinical diagnosis and treatment onset to the last date of illness with any of the following criteria:
1. Respiratory rate according to age and IMCI criteria
2. No danger signs or subcostal recession
3. No fever (temperature < 38.0 °C or < 37.50 °C if < 2 month old)

Key secondary outcome(s)
1. Incidence of further episodes within 3 months or relapse of pneumonia (The Integrated Management of Childhood Illness [IMCI] defined rapid breathing and cough)
2. Rate of failure to respond to treatment or worsening condition rate (as defined by protocol)

Completion date
30/05/2007

Eligibility

Key inclusion criteria
Any child, living in the defined areas of Kabul (within the catchment area of the Maywand Teaching Hospital), between 1 week and 18 complete months of age.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 Weeks

Upper age limit
18 Months

Sex
Not Specified

Key exclusion criteria
1. >8 hours after the start of hospital antibiotics treatment
2. Living outside of the study areas of Kabul and childs families expect to move away within the next 3 months
3. If the child has been diagnosed with clinical rickets or known to have received a course of high dose vitamin D treatment in the past 3 months (doses as high as 300,000 IU are used routinely in India and Pakistan, and thus rarely, some recently returned returnee children may have recently received such doses)
4. If have symptoms of very severe pneumonia (according to IMCI definitions of very severe pneumonia) or other illnesses as the major diagnosis occurring at the same time as pneumonia, such as meningitis, major heart or renal defect, active measles, severe malnutrition requiring separate medical treatment, and suspected tuberculosis
5. Child with severe diarrhoea or vomiting
6. Wheeze at the time of diagnosis (if wheeze develops later the child continues to be in the study)
7. Caretakers do not give consent

Date of first enrolment
09/12/2006

Date of final enrolment
30/05/2007

Locations

Countries of recruitment

Afghanistan

Study participating centre
Aga Khan Health Services Afghanistan
Kabul
Afghanistan
-

Sponsor information

Organisation
Aga Khan Health Services Afghanistan (Afghanistan)

Funder(s)

Funder type
Government

Funder Name
New Zealand Aid and International Development Agency (New Zealand)

Funder Name
In kind donations from Aga Khan Development Network and Maywand Teaching Hospital (funded by the Government of Afghanistan) (Afghanistan)

Results and Publications

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	01/01/2008		Yes	No